EPA Reg. No. 88867-1

Material Sent for Data Extraction

Reg. # 88607-R

Description: Log

☑ Material(s) Sent to Data Extraction Contractors:

- ☑ New Stamped Label Dated 6/6/13
- ☐ Notification Dated _____
- ☑ New CSF(s) Dated 2/21/12
- ☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Urbanski

Phone: 347-0156 Division: RD

Date: 6/6/13

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
88867-1	JUN 0 6 2013

Term of Issuance:
Conditional

Name of Pesticide Product:
Protector 0.5G

Name and Address of Registrant (include ZIP Code):
Willapa-Grays Harbor Oyster Growers Association
P.O. Box 3, Ocean Park, WA 98640

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(a). You must:

1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

2. Submit or cite any data which have previously been required for imidacloprid.

3. Make the following label change before you release the product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No 88867-1."

Signature of Approving Official:

John Hebert, Product Manager 07
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date: JUN 0 6 2013

EPA Form 8570-6

4. Note that monitoring data reporting is required under the National Pollutant Discharge Elimination System (NPDES) permit. We request that you submit this information to the Registration Division, Office of Pesticide Programs, as well.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the CSF currently on file for this product is the basic CSF, dated 2/21/12.

If you have any questions, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Draft Label

ACCEPTED
JUN 0 6 2013
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

GROUP 4A INSECTICIDE

EPA. Reg. No: 88867-1

PROTECTOR 0.5G

FOR USE ONLY IN WILLAPA BAY/ GRAYS HARBOR, WASHINGTON, TO CONTROL BURROWING SHRIMP IN COMMERCIAL SHELLFISH BEDS

ACTIVE INGREDIENT:	
Imidacloprid: 1-[(6-Chloro-3-pyridiny) methyl]-N-nitro-2-imidazolidinimine	0.5%
OTHER INGREDIENTS:	99.5%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION-CAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No.

EPA Establishment No.

FIRST AID	
If in eyes:	• Hold eye open and rise slowly and gently with water for 15-20 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice

Have the product container or label with you when calling poison control center or doctor or going for treatment. You may also 1-800-222-1222 for emergency medical treatment information.

NOTE TO PHYSICIAN

No specific antidote is available. Treat the patient symptomatically

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton
- Shoes and socks
- Protective eyewear
- Dust mask

Follow manufacturer's instructions for cleaning/maintaining PPE. If instructions for washables do not exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENTS

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users Must:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to wildlife and highly toxic to aquatic invertebrates.

DIRECTIONS FOR USE

It is a violation of the Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time the product is applied.

READ THIS LABEL: Read the entire label and follow all use directions and precautions.

For use only to control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor]

MIXING INSTRUCTIONS:

Do NOT formulate this product into other end-use products.

APPLICATION INSTRUCTIONS:

To control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor], apply at a maximum rate of 0.5 lb a.i. imidacloprid/acre per year.

Apply this product uniformly over the area being treated using drop-type or rotary–type spreaders. Do not use spreaders that would apply the material in narrow, concentrated bands. All spreader equipment must be calibrated at the time of application to achieve desired application rate.

Use one of the following properly calibrated application equipment:

- Conventional granular pesticide applicators ("belly grinders").
- Helicopters equipped with boom ¾ as long as rotor diameter.
- Ground based vehicles equipped with spinners or drop spreaders.

RESTRICTIONS:

- Do not harvest shellfish within 30 days after treatment.
- All ground must be properly staked and flagged to protect adjacent shellfish and water areas. For aerial applications, the corners of each plot must be marked so the plot is visible from an altitude of at least 500ft.
- A single application of imidacloprid at up to 0.5 ai per acre per year is allowed.
- No adjuvants or surfactants are allowed with the use of this product.
- Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.
- All applications must occur between April 15 and December 15.
- A 100-foot buffer zone must be maintained between the treatment area and the nearest shellfish to be harvested within 30 days when treatment is by aerial spray; a 25 foot buffer zone is required if treatment is by hand spray if nearest shellfish bed is to be harvested within 30 days.
- Do not apply aerially during Federal holiday weekends. During aerial applications, all public access areas within one-quarter (1/4) mile and all public boat launches within quarter (1/4) mile radius of any bed scheduled for treatment shall be posted. Public access areas shall be posted at 500 feet intervals at those access areas more than 500 feet wide. Signs shall be a minimum of 8 ½ x 11 inches in size, and be made of a durable weather-resistant, white material. The sign will say "Imidacloprid will be applied for burrowing shrimp control on [date] on commercial shell fish beds. Do not Fish, Crab or Clam within one-quarter mile of the treated area." The location of the treated area will be included on the sign.

The sign will include lettering shall be in bold black type with the word "WARNING" or "CAUTION" at least one-fourth (1/4) of an inch high. Signs shall be posted so they are secure from the normal effects of weather and water currents, but cause no damage to private property. Signs shall be posted at least 2 days prior to treatment and shall remain for at least 30 days after treatment.

DRIFT MANAGEMENT:

The interaction of many equipment and weather related factors determine the potential for product drift. Average wind speed at the time of application is not to exceed 10 mph to minimize drift to adjacent shellfish and water areas when applied by air. Drift potential increases at wind speeds of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors including height of granular spreader above the tideflat and equipment specifications determine drift potential at any given wind speed. Do NOT apply when winds are greater than 10 mph or during temperature inversions. Make applications at the lowest possible height (helicopter, ground or barge) that is safe to operate and reduces exposure of the granules to wind. When applications are made crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the treatment area, the applicator must compensate for this displacement by adjusting the path of the application equipment upwind. Swath adjustment distance should increase with increasing drift potential.

Mixing and Loading Requirements

The use of a properly designed and maintained containment pad for mixing and loading of any pesticide into application equipment is recommended. If containment pad is not used, maintain a minimum distance of 25 feet between mixing and loading areas and potential surface to groundwater conduits such as field sumps, uncased well heads, sinkholes, or field drains.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved wasted disposal facility.

Pesticide Storage: Store in a cool, dry place an in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If material is spilled for any reason or cause, carefully contain any spilled material to prevent non-target contamination. Do not walk through spilled material and dispose of as directed for pesticides above. Refer to Precautionary Statements on label for hazards associated with handle of this material. In spill or leak incidents, keep unauthorized people away. For chemical spill, leak, fire, or exposure, you may contact CHEMTREC at 800-424-9300.

Container Disposal: Non-Refillable: Do not reuse or refill this container. Completely empty bag into application equipment. Dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

This product is registered by the Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form

United States Environmental Protection Agency Washington, DC 20460

[X] Registration [X] Amendment [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 88867 - R
2. EPA Product Manager:
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Protector 0.5G
PM#: 1
5. Name and Address of Applicant *(Include ZIP Code)*:
Willapa-Grays Harbor Oyster Growers Association
P.O. Box 3, Ocean Park, WA 98640
[ ] *Check if this is a new address*
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 228-501
Product Name Mallet 0.5G Insecticide

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated
[X] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is an application for a me-too registration and amendment to add control of burrowing shrimp and ghost shrimp in oyster beds in Willapa Bay and Grays Harbor, Washington, USA. IR-4 is filing a petition to support establishment of a tolerance in shellfish (no group name 99, Monograph Number 000).

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) Retail Container:
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alan Schreiber	Designated Agent	509-260-4348

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Alan Schreiber
3. Title: Designated Agent
4. Typed Name: Alan Schreiber
5. Date: 2/1/2012

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

The IR-4 Project
Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540
732.932.9575
fax: 609.514.2612
ir4.rutgers.edu

February 7, 2012

Ms. Barbara Madden
EPA-OPP-Document Processing (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Dear Barbara:

RE: Imidacloprid
Protector 0.5G, EPA Registration No. pending
Protector 2F, EPA Registration No. pending
Imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl) methyl]- *N* -nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid

New Uses:

Description	IR-4 PR No.	Source of New Tolerance
Fish-shellfish, mollusc	10553	Volume 2
Fish	none	Volume 2 and approved waiver request for fish uptake and metabolism study

FEE CATEGORY: R170
REGISTRATION FEE: $119,952 (See IR-4 Exemption Request below)
Electronic Submission to Follow

The undersigned, Dr. Keith Dorschner, Entomology Program Manager, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Station of Washington submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, imidacloprid (40 CFR 180.472).

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

List of Studies Submitted in Support of Proposed Tolerances for imidacloprid:

Vol. No.	Volume Title
2	Imidacloprid: Magnitude of the Residue on Oyster
3	IR-4 Minor Use Submission in Support of Tolerances for Imidacloprid In or On Fish and Shellfish (note: this is a volume of non-GLP studies and reports provided to IR-4 in support of the registration)

I request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

The toxicological database for imidacloprid is complete, with the exception of an immunotoxicity study. The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system.

An immunotoxicity study is required as a part of new data requirements in 40 CFR Part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. Therefore, a database uncertainty factor (UFDB) is not needed to account for lack of this study. EPA has determined that reliable data show the safety of infants and children would be adequately protected with a 1X FQPA SF for all exposure scenarios, except acute dietary (all populations).

A developmental neurotoxicity study was performed with imidacloprid and well-defined NOAELs were achieved in the study.

A fish uptake and metabolism study has not been performed for imidacloprid; however, a waiver has been submitted to EPA and approved. See Volume 3 for the waiver rationale. ChemSAC approval of the waiver is provided in Section G of the petition (Volume 1). A tolerance on fish is proposed in Section F of the petition. EPA may consider this tolerance request appropriate if there are concerns about inadvertent residues in fish as a result of oyster bed treatments.

I also submit the following in support of the proposed tolerances for imidacloprid:

1. Notice of Filing
2. EPA Form 8570-1 (Protector 0.5G)
3. EPA Form 8570-1 (Protector 2F)
4. EPA Form 8570-27 (Mallet 0.5G)
5. EPA Form 8570-27 (Imidacloprid 2F Insecticide/Nuprid 2SC)
6. EPA Form 8570-34 (Protector 0.5G)
7. EPA Form 8570-34 (Protector 2F)
8. EPA Form 8570-35 (Protector 0.5G) Agency and Public copies
9. EPA Form 8570-35 (Protector 2F) Agency and Public copies
10. Protector 2F draft label (5 copies)
11. Protector 0.5G draft label (5 copies)

The following non-GLP studies were provided to IR-4 in support of the registration. They are found in Volume 3.

1. Experimental Applications of Imidacloprid to Control Burrowing Shrimp at the Commercial Scale: 2008
2. Field Trials of Imidacloprid on Burrowing Shrimp, 2009
3. Rationale for Waiving the Need for a Fish Uptake and Metabolism Study
4. Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) using Sheepshead Minnows
5. Assessing the Hazards of Imidacloprid to Non-Target Fishes
6. Development of a new method for the determination of residues of the neonicotinoid insecticide Imidacloprid in juvenile Chinook (*Oncorhynchus tshawytscha*) using ELISA detection
7. Final Report – December 2011 Non-Target Effects of Imidacloprid on Dungeness crab in Willapa Bay, Washington 2008 to 2011
8. Impact of imidacloprid on epi-benthic and benthic invertebrates: Initial studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp
9. Impact of imidacloprid on epi-benthic and benthic invertebrates: Preliminary small plot studies, 2006-07
10. Studies on the non-target effects of imidacloprid on Dungeness crab in Willapa Bay, Washington
11. SUPPLEMENT Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) Using Sheepshead Minnows – Draft Report submitted by Nautilus Environmental, LLC to the University of Washington
12. Ecological Risk Assessment of Imidacloprid Applications to Control Burrowing Shrimp in Oyster Beds of Willapa Bay and Grays Harbor, WA

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per _____

Keith Dorschner, Ph.D.
Entomology Program Manager
Rutgers, the State University of NJ
500 College Road East, Suite 201 W
Princeton, NJ 08540

cc: Alan Schreiber
RFC (transmittal letter, petition)

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Willapa-Grays Harbor Oyster Growers Assoc., P.O. Box 3, Ocean Park, WA 98640 (xxx-xxx-xxxx)	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 2/1/2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Aquatic Food Crop	Product Name Protector 0.5G

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 2/12/2012	Typed or Printed Name and Title Alan Schreiber

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Willapa-Grays Harbor Oyster Growers Association P.O. Box 3 Ocean Park, WA 98640	88801-R
	Product Name Protector 0.5G
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 2/21/12

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☑ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid	Mallet 0.5G Insecticide	228-501
Signature	Name and Title	Date
	Alan Schreiber	02/01/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date **August 31, 2012**	EPA Reg. No./File Symbol **88867 - R**	Page 1 of 5
Applicant's/Registrant's Name & Address: **Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640**	Product **Protector 0.5G**	
Ingredient(s): **imidacloprid (PC Code 129099)**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	**SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES**				
	Series 61 & 62 Data Requirements				
830.1550 / 61-1	Product Identity and Composition	46801101	Nufarm (000228)	PER	
830.1600 / 61-2	Description of the Materials Used to Produce the Product	46801101	Nufarm (000228)	PER	
830.1650 / 61-2	Description of the Formulation Process	46801101	Nufarm (000228)	PER	
830.1670 / 61-3	Discussion of the Formation of Impurities	46801101	Nufarm (000228)	PER	
830.1700 / 62-1	Preliminary Analysis	46801102	Nufarm (000228)	PER	
830.1750 / 62-2	Certified Limits	46801102	Nufarm (000228)	PER	
830.1800 / 62-3	Enforcement Analytical Method	46801102	Nufarm (000228)	PER	
	Series 63 (Phys/Chem Properties) Data Requirements				
830.6302 / 63-2	Color	46801103 / 46801104	Nufarm (000228)	PER	
830.6303 / 63-3	Physical State	46801103 / 46801104	Nufarm (000228)	PER	
830.6304 / 63-4	Odor	46801103 / 46801104	Nufarm (000228)	PER	
830.7200 / 63-5	Melting Point	--	--	NR	Footnote 1
830.7220 / 63-6	Boiling Point	--	--	NR	Footnote 2
830.7300 / 63-7	Density, Bulk Density, Specific Gravity	46801103 / 46801104	Nufarm (000228)	PER	
830.7520	Particle Size	--	--	NR	Footnote 3
830.7840 / 63-8	Solubility	--	--	NR	Footnote 4
830.7950 / 63-9	Vapor Pressure	--	--	NR	Footnote 5
830.7370 / 63-10	Dissociation Constant	--	--	NR	Footnote 6
830.7570 / 63-11	Partition Coefficient	--	--	NR	Footnote 7

Signature	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867 -	Page 2 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640	Product Protector 0.5G	

Ingredient(s): imidacloprid (PC Code 129099)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES				
830.7000 / 63-12	pH	--	--	NR	Footnote 8
830.7050	UV/Visible Absorption	--	--	NR	Footnote 9
830.6313 / 63-13	Stability to normal / elevated temperatures, metals and metal ions	--	--	NR	Footnote 10
830.6314 / 63-14	Oxidizing/Reducing Reaction	--	--	NR	Footnote 11
830.6315 / 63-15	Flammability	--	--	NR	Footnote 12
830.6316 / 63-16	Explodability	--	--	NR	Footnote 13
830.6317 / 63-17	Storage Stability	47074201	NUFARM (000228)	PER	
830.7100 / 63-18	Viscosity	--	--	NR	Footnote 14
830.6319 / 63-19	Miscibility	--	--	NR	Footnote 15
830.6320 / 63-20	Corrosion Characteristics	47074201	NUFARM (000228)	PER	
830.6321 / 63-21	Dielectric Breakdown Voltage	--	--	NR	Footnote 16

FOOTNOTES

1. Melting Point (830.7200) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
2. Boiling Point (830.7220) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
3. Particle Size (830.7520) data are not required for Protector 0.5 G 40 CFR §158.310(f) (23).
4. Solubility (830.7840) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
5. Vapor Pressure (830.7950) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
6. Dissociation Constant (830.7370) data are not required since Protector 0.5 G is an End use product 40 CFR § f58.310 (e).
7. Partition Coefficient (830.7570) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
8. pH (830.7000) data are not required since Protector 0.5 G is not soluble/dispersible in water 40 CFR §158.310 (e).
9. UV/Visible Absorption (830.7050) data are not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
10. Stability (830.6313) data is not required since Protector 0.5 G is an End use product 40 CFR §158.310 (e).
11. Oxidizing/Reducing Reaction (830.6314) data are not required since Protector 0.5G does not contain an oxidizing or reducing agent 40 CFR §158.310 (e) (13)

Signature	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012

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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date **August 31, 2012**	EPA Reg. No./File Symbol **88867 -**	Page 3 of 5
Applicant's/Registrant's Name & Address: **Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640**	Product **Protector 0.5G**	

Ingredient(s): **imidacloprid (PC Code 129099)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES				

12. Flammability data are not required since **Protector 0.5G** does not contain combustible liquids 40 CFR §158.310 (e) (14).
13. Explodability data are not required since **Protector 0.5G** is not potentially explosive components 40 CFR §158.310 (e) (15).
14. Viscosity (830.7100) data is not required since **Protector 0.5 G** is not a liquid End use product 40 CFR §158.310 (e) (19).
15. Miscibility (830.6319) data are not required since **Protector 0.5 G** is not an emulsifiable liquid for dilution with petroleum solvents 40 CFR §158.310 (f)(16).
16. Dielectric Breakdown Voltage (830.6321) data are not required since **Protector 0.5 G** is not for use around electrical equipment 40 CFR §158.310 (f)(17).

Signature	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867 -	Page 4 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640	Product Protector 0.5G	
Ingredient(s): Imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 870	SUBPART F: HEALTH EFFECTS TEST GUIDELINES				
	Acute Toxicity Data Requirements				
870.1100 / 81-1	EP- Acute Oral Toxicity (RAT)	46801105	NUFARM (000228)	PER	
870.1200 / 81-2	EP- Acute Dermal Toxicity	46801106	NUFARM (000228)	PER	
870.1300 / 81-3	EP- Acute Inhalation Toxicity (waiver request)	46801107	NUFARM (000228)	PER	
870.2400 / 81-4	EP- Primary Eye Irritation	46801108	NUFARM (000228)	PER	
870.2500 / 81-5	EP- Primary Skin Irritation	46801109	NUFARM (000228)	PER	
870.2600 / 81-6	EP- Skin Sensitization	46801110	NUFARM (000228)	PER	

FOOTNOTES

Signature	Name and Title:	Date
	Alan Schreiber, Designated Agent	August 31, 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date **August 31, 2012**	EPA Reg. No./File Symbol **88867 -**
Applicant's/Registrant's Name & Address: **Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640**	Product **Protector 0.5G**

Ingredient(s): **imidacloprid (PC Code 129099)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
Imidacloprid Generic Data Requirements					

Addressed via Formulators Exemption *(40 CFR 152.85)*

FOOTNOTES

Signature	Name and Title:	Date
	Alan Schreiber, Designated Agent	August 31, 2012

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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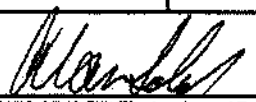
DATA MATRIX

Date 2/1/2012	EPA Reg No./File Symbol Comapny Number Pending	Page 1 of 1
Applicant's/Registrant's Name & Address Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640	Product Protector 0.5G	

Ingredient Imidacloprid CAS No. 138261-41-3

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
1	Chemical Identity	46801101	228	PER	
2	Statement of Composition	46801101	228	PER	
3	Formation of Impurities	46801101	228	PER	
1	Preliminary Analysis	46801102	228	PER	
2	Certification of Limits	46801102	228	PER	
3	Analytical Method	46801102	228	PER	
17	Storage Stability	47074201	228	PER	
20	Corrosion Characteristics	47074201	228	PER	
1	Acute Oral Toxicity Rat	46801105	228	PER	
2	Acute Dermal Toxicity Rat/Rabbit	46801106	228	PER	
3	Acute Inhalation Rat	46801107	228	PER	
4	Primary Eye Irritation -- Rabbit	46801108	228	PER	
5	Primary Dermal Irritation -- Rabbit	46801109	228	PER	
8	Dermal Sensitization -- Guinea Pig	46801110	228	PER	

Signature	Name and Title	Date
	Alen Schreiber, Designated Agent	02/01/2012

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date 2/1/2012	EPA Reg No./File Symbol Comepny Number Pending	Page 1 of 1
Applicant's/Registrant's Name & Address Willapa-Grays Harbor Oyster Growars Association, P.O. Box 3, Ocean Park, WA 98640	Product Protector 0.5G	

Ingredient Imidacloprid CAS No. 138261-41-3

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	
			228	PER	

Signature	Name and Title	Date
	Alan Schreiber, Designated Agent	02/01/2012

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Decision #: 461090
DP #: (404444)
PRIA
Parent DP #:
Submission #: 911544
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 09-Aug-2012

R170.0 #30992

* * * Registration Information * * *

Registration: 88867-R - PROTECTOR 0.5G

Company: 88867 - WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Jennifer Urbanski JURBANSK

Sent Date: _____ PRIA Due Date: 06-Jun-2013 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R170.0) NEW USE;EACH ADDITIONAL NEW FOOD USE;NO FEE: LINKED TO A PRIA APF

Ingredients: 129099, Imidacloprid(.5%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 09-Aug-2012 Due Back: _____

DP Ingredient: 129099, Imidacloprid

DP Title: _____

CSF Included: ● Yes ◯ No Label Included: ● Yes ◯ No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	RD / TRB			Last Possible Science Due Date: 08-Dec-2012
Team Name:	TOX			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Attn AT Reviewer: Please review CSFs for 88867-R and 228-501 to determine if they are substantially similar. Attached are the two CSFs, 88867-R label, data matrix, and cover letter. Thanks!

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

TECHNICAL REVIEW BRANCH
SIMILARITY DETERMINATION

04/DEC/2012

MEMORANDUM

Subject:	Name of Pesticide Product:	Protector 0.5G
	EPA Reg. No. /File Symbol:	88867-R
	DP Barcode:	D404444
	Decision No:	461090
	Action Code:	R170.0
	PC Codes:	129099 (imidacloprid)
From:	Eugenia McAndrew, Biologist Technical Review Branch Registration Division (7505P)	
To:	Jennifer Urbanski, RM Team 01 Insecticide-Rodenticide Branch Registration Division (7505P)	
Applicant:	Willapa-Grays Harbor Oyster Growers Association P.O. Box 3 Ocean Park, WA 98640	

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Imidacloprid	0.5
Other Ingredients:	99.5
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please review CSFs for 88867-R and 228-501 to determine if they are substantially similar."

BACKGROUND: Willapa-Grays Harbor Oyster Growers Association has applied for registration of Protector 0.5G, EPA File Symbol 88867-R, claiming similarity to Mallet 2.5G Insecticide, EPA Reg. 228-501. Both products contain imidacloprid - 0.5% in the proposed product and 2.5% in the cited product. The submission includes a basic CSF dated February 21, 2012, a label, data matrix and company letter.

The data matrix cites acute toxicity studies with MRIDs 468011-05 to -10. A search of the OPP electronic databases shows that these studies were submitted to support the registration of both 228-501 (0.5% a.i.) and 228-502 (2.5% a.i.). They were reviewed and classified as acceptable by TRB (McAndrew; D328444; EPA File Symbol 228-LNE; 11/MAY/2006).

RECOMMENDATIONS:

1. TRB compared the basic CSFs of the proposed product, 88867-R, and the cited product, 228-501, and determined that the two formulations are toxicologically similar in composition. The acute toxicity data referenced above maybe used to support the proposed product. However, the two products are not similar in labeling.

2. The acute toxicity profile for the proposed product, Protector 0.5G, EPA File Symbol 88867-R, is as follows:

acute oral toxicity	IV	cited	MRID 46801105
acute dermal toxicity	IV	cited	MRID 46801106
acute inhalation toxicity	IV	cited	MRID 46801107
primary eye irritation	III	cited	MRID 46801108
primary skin irritation	IV	cited	MRID 46801109
dermal sensitization	negative	cited	MRID 46801110

3. The proposed basic CSF submitted for 88867-R must be reviewed and accepted by the TRB Product Chemistry Team.

4. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 088867-00001

PRODUCT NAME: Protector 0.5G

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Avoid contact with eyes or clothing. [Wear protective eyewear.]* Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

*[Protective eyewear may be specified, if appropriate.]

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Decision #: 461090
DP #: (404445)
PRIA
Parent DP #:
Submission #: 911544
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 09-Aug-2012

R120.0 #430996

* * * Registration Information * * *

Registration: 88867-R - PROTECTOR 0.5G

Company: 88867 - WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Jennifer Urbanski JURBANSK

Sent Date: _____ PRIA Due Date: 06-Jun-2013 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R170.0) NEW USE;EACH ADDITIONAL NEW FOOD USE;NO FEE: LINKED TO A PRIA APP

Ingredients: 129099, Imidacloprid(.5%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 09-Aug-2012 Due Back: _____

DP Ingredient: 129099, Imidacloprid

DP Title: _____

CSF Included: ● Yes ◯ No Label Included: ● Yes ◯ No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	RD / TRB			Last Possible Science Due Date: 08-Dec-2012
Team Name:	CHEM			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Attn PC reviewer: Please determine if the CSFs for 88867-R and 228-501 are substantially similar. Attached are the two CSFs, and the label, data matrix, and cover letter for the new product. Thanks!

Note: The data matrix does not currently list the Group B data citations, we're getting a new one, the MRIDs are 46801103 and 46801104.

Urbanski, Jennifer

From: aschreib@centurytel.net
Sent: Wednesday, May 29, 2013 5:55 PM
To: Urbanski, Jennifer
Subject: Re: labels for 88867-R and -E
Attachments: Federal 2F Label Ver 9 May 29 2013.doc; Federal__0_5G_Label Ver 8 May 29 2013.doc

Jennifer,

We have made all requested changes except we cannot figure out what our EPA registration number is. I will contact someone at EPA first thing tomorrow and track it down; otherwise, every thing should be in proper order. Scroll down for some answers to your questions.

From: Urbanski, Jennifer
Sent: Wednesday, May 22, 2013 10:45 AM
To: aschreib@centurytel.net
Subject: labels for 88867-R and -E

Hi Alan, below are some required label revisions and a few clarifying questions. Can you please send me the revised labels by Tuesday? Thanks!

Jenn

88867-R

1) On page 1, delete "Not for sale.... Association" and replace with "For use only in Willapa Bay/Grays Harbor, WA, to control burrowing shrimp in commercial shellfish beds."
2) Please add in the EPA Establishment # and the company name and address.
3) On page 2 in the First Aid statements, if in eyes must be first. If on skin and clothing is not needed, but if you choose to keep it it must be underneath if in eyes.
4) On page 2 in the First Aid box, above Note to Physician, add "Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX [add in number here) for emergency medical treatment information."
5) On page 2 move "Hazards to Humans and Domestic Animals" below "Precautionary Statements".
6) On page 2 delete "when working in a non-ventilated space" from the PPE section.
7) Throughout the label, you reference oyster beds but you also mention other organisms, like clams. For clarity, change references from "oyster beds" to "commercial shellfish beds".
8) On page 2, "Application INSTRUCTIONS" is misspelled.
9) On page 2, change "...maximum rate of 0.5 lb a.i./acre of imidacloprid..." to read ""...maximum rate of 0.5 lb a.i. imidacloprid/acre ..."
10) On page 2, change "Avoid the use of spreaders that would..." to read "Do not use spreaders that would...."
11) On page 2, change "All spreader equipment should be calibrated..." to read "All spreader equipment must be calibrated..."
12) On page 2, change "Do not harvest clams or oysters..." to read "Do not harvest shellfish..."
13) On page 2, please correct the following sentence (see bold addition): "Public access areas shall be posted at 500 feet intervals at those access areas more than 500 feet wide."
14) On page 3, as the PHI is 30 days, change "... shall remain for at least 3 days after treatment" to read "....shall remain for at least 30 days after treatment".
15) On page 3 in the Storage and Disposal section, after container disposal, add "non-refillable. Do not reuse or refill this container."

16) On page 3 in the Storage and Disposal section, add "Pesticide Storage:" before the last two paragraphs and move this section under the statement "DO not contaminate..."

88867-E

1) On page 1, delete "Not for sale.... Association" and replace with "For use only in Willapa Bay/Grays Harbor, WA, to control burrowing shrimp in commercial shellfish beds."
2) Please add in the EPA Establishment # and the company name and address.
3) On page 2 in the First Aid statements, if in eyes statement is not needed and you may delete it if you wish.
4) On page 2 in the First Aid box, above Note to Physician, add "Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX [add in number here] for emergency medical treatment information."
5) On page 2 move "Hazards to Humans and Domestic Animals" below "Precautionary Statements".
6) On page 2, delete the text in the Hazards to Humans section and replace with the following: "Harmful is swallowed. Harmful if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist."
7) On page 2 delete "when working in a non-ventilated space" from the PPE section.
8) Throughout the label, you reference oyster beds but you also mention other organisms, like clams. For clarity, change references from "oyster beds" to "commercial shellfish beds".
9) On page 2, change "...maximum rate of 0.5 lb a.i./acre of imidacloprid..." to read ""...maximum rate of 0.5 lb a.i. imidacloprid/acre ..."
10) On page 2, change "Do not harvest clams or oysters..." to read "Do not harvest shellfish..."

Clarifying questions

1) Where did you get the Environmental Hazards language from? They differ between the two labels. Although this is supposed to be confidential, I doubt it is any big deal to EPA. [redacted]
2) Where did the spray drift language come from on each label? Is it on another label? Same story. [redacted].

Jennifer Urbanski, Ph.D., Biologist
Insecticide-Rodenticide Branch, 57221
Registration Division (7505P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
(703) 347-015

Urbanski, Jennifer

From: Jonathan Peterson [jpeterson@centurytel.net]
Sent: Tuesday, June 04, 2013 3:29 PM
To: Urbanski, Jennifer
Cc: Hebert, John
Subject: RE: Willapa-Grays Harbor Oyster Growers Association
Attachments: Federal__0_5G_Label Ver 8 May 29 2013_jmucomments 6.4.2013.doc; Federal 2F Label Ver 8 April 9 2012 6.4.2013.doc

Here are the cleaned up version, I must have clicked on something wrong, my apologizes. If you need anything else please let me know.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

From: Urbanski, Jennifer [mailto:urbanski.jennifer@epa.gov]
Sent: Tuesday, June 04, 2013 12:20 PM
To: Jonathan Peterson
Cc: Hebert, John
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Hi Jonathan, the labels still aren't the clean versions (all blue/red underlined text should be converted to plain black text like you would see in a regular label and red strikeouts should be deleted]. Can you please send these updated labels to both me and John Hebert? Thank you!

Jenn

From: Jonathan Peterson [mailto:jpeterson@centurytel.net]
Sent: Tuesday, June 04, 2013 2:04 PM
To: Urbanski, Jennifer
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Good morning Jennifer, here are the updated and cleaned up versions of the two documents you requested. If you need anything else, please let me know. Thank you.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

From: Urbanski, Jennifer [mailto:urbanski.jennifer@epa.gov]
Sent: Tuesday, June 04, 2013 6:23 AM
To: Jonathan Peterson
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Also, you still need the EPA Establishment # placeholder on the 2F product, in addition to the company address.... Also, the address you have on the 0.5G label is not the same as the address on the registration application, which is P.O. box 3, Ocean Park, WA 98640. Which is correct? Be sure the correct one is on both labels.

From: Jonathan Peterson [mailto:jpeterson@centurytel.net]
Sent: Monday, June 03, 2013 12:03 PM
To: Urbanski, Jennifer
Subject: Willapa-Grays Harbor Oyster Growers Association

Jennifer, here is the latest changes for the two documents you requested. We are just waiting to hear back about the EPA establishment number. If you have any questions please let me know. Thank you.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.:404445 **DECISION No.: 461090** **ACTION CODE: R170**
PC Code(s): 129099 **EPA Reg. No. 88867-R** **FOOD USE: Yes**

DATE: **November 30, 2012**

SUBJECT: **Product Name: Protector 0.5G**

FROM: **Akiva Abramovitch, Ph. D.**
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

12/4/12

TO: **Jennifer Urbanski/Venus Eagle, PM 01**
Insecticide/Rodenticide Branch/RD (7505P)

Registrant Name: Willapa Grays Harbor Oyster Growers Association
Formulation Type: Granular

INTRODUCTION:

The applicant requested a "me-too" registration of subject product claiming its similarity (identical) to Mallet 0.5G Insecticide, EPA Reg. No. 228-501. In support of the application, the applicant cited product chemistry data of EPA Reg. No. 228-501 and provided an authorization letter from Nufarm to use their data. Also submitted a basic CSF dated February 21, 2012 and a proposed label.

FINDINGS:

1. The subject product was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 0.5% Imidacloprid Technical.

2. [redacted]

3. The label claim nominal concentrations of 0.5% Imidacloprid is consistent with that in the basic CSF, both are in compliance with the regulations of PR Notice 91-2.

4. A Since the label lists food uses the ingredients were approved for food uses under 40CFR 180.920

CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar in composition and labeling to EPA Reg. No. 228-501

2 Based on the finding of 1. above, the TRB will have no objections for the use of the data from Legion 80 WDG Fungicide, EPA Reg. No. 228-501 and for the "me-too" registration of the subject product.

3. The basic CSF dated February 21, 2012 is acceptable.

4. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 7-MAR-2013

SUBJECT: **Imidacloprid.** Section 3 Request for use on Oyster Beds in Washington (WA), and Section 18 Emergency Exemption Request for use on Sugarcane in Louisiana (LA). **Human-Health Risk Assessment.**

PC Code: ~~129099~~
Decision Nos.: 461091 and 472398
Petition Nos.: 2E7988 and 12LA11
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: NA
DP Barcodes: D399719 and D407172
Registration No.: xxx-xxx, xxx-xxx, 264-758
Regulatory Action: Section 3 Registration
Case No.: 7605
CAS No.: 138261-41-3
40 CFR: §180.472

FROM: Jennifer R. Tyler, Chemist
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Risk Assessment Branch 1 (RAB1)/Health Effects Division (HED; 7509P)

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THROUGH: George F. Kramer, Ph.D., Branch Senior Scientist
Dana M. Vogel, Deputy Division Director
RAB1/HED (7509P)

TO: Sidney Jackson/Barbara Madden
Tawanda Maignan/Debra Rate
Registration Division (RD; 7505P)

The HED of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The RD of OPP has requested that HED evaluate hazard and exposure data and conduct dietary, occupational, residential and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from the following: 1) the Section 3 request for the use of the active ingredient (ai) imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) on oyster beds in Willapa Bay and Grays Harbor in WA; and 2) the Section 18 Emergency Exemption request for the use of imidacloprid on sugarcane in LA. A summary of the findings and an assessment of human-health risk resulting from the aforementioned uses are provided in this document. The risk assessment, residue chemistry data review, dietary exposure assessment, and occupational exposure assessment (sugarcane use) were provided by Jennifer Tyler (RAB1); the hazard characterization and endpoint selection by Chester Rodriguez (RAB1); the occupational exposure assessment (oyster bed use) and

residential exposure assessment by Matthew Crowley (CEB); and the drinking water exposure assessment by José Melendez of the Environmental Fate and Effects Division (EFED).

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1.0 Executive Summary

Background: Imidacloprid is an insecticide registered for uses on a variety of crops for the control of aphids, cucumber beetles, and whiteflies (including sweet potato or silverleaf whitefly). It is a member of the pyridylmethylamine class of compounds. Its mode of action involves disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid blocks the signals that are induced by acetylcholine at the post-synaptic membrane, resulting in normal nerve function impairment.

Imidacloprid is registered for use on several agricultural products, ornamental turf/plant products, seed treatments, pet care products, as well as structural pest products. Tolerances are currently established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, under 40 CFR §180.472 in/on various plant and livestock commodities.

The Interregional Research Project No. 4 (IR-4) has submitted a petition (PP# 2E7988) for the use of imidacloprid on oyster beds to control burrowing shrimp. IR-4 has requested to add this use to the following labels: Protector® 0.5G [a granular (G) product containing 0.5% imidacloprid as the active ingredient (ai); EPA Reg. No. xxx-xxx], and Protector® 2F [a flowable concentrate (F) formulation containing 21.4% imidacloprid as the ai; EPA Reg. No. xxx-xxx]. In conjunction with this petition, tolerances have been requested for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on fish at 0.05 ppm, and fish-shellfish, mollusc at 0.05 ppm.

In addition, the Louisiana Department of Agriculture and Forestry (LDAF) has submitted a Section 18 Emergency Exemption request for the use of imidacloprid on sugarcane in LA.

Hazard Assessment: The main targets of toxicity following oral administration of imidacloprid in mammalian systems were the nervous system and the thyroid. The most sensitive species tested was the rat. Evidence of neurotoxicity was reported in the rat acute neurotoxicity (ACN) study as changes in clinical signs and functional-observation battery (FOB) measurements, including decreased motor and locomotor activities, tremors, gait abnormalities, increased righting reflex impairments and body temperature, decreased number of rears and response to stimuli, and decreases in forelimb and hindlimb grip strength. Also, in a rat developmental neurotoxicity (DNT) study where imidacloprid was administered to pregnant/lactating dams in the diet, there were decreases in offspring motor activity measurements and a small but statistically significant decrease in the caudate/putamen width in the brain of female pups. No neurotoxic effects were reported in any other toxicity study including the rat subchronic neurotoxicity study.

Long-term dietary exposure to imidacloprid in a rat chronic toxicity study resulted in an increased incidence of mineralized particles in the thyroid colloid, and there were no effects reported in the rabbit dermal or rat inhalation studies.

There was no evidence of increased qualitative or quantitative susceptibility in either rats or rabbits based on the results of prenatal developmental toxicity studies or a two-generation reproductive toxicity studies in rats. In the rat DNT study, however, the neurotoxic offspring effects noted above occurred in the presence of only maternal food consumption and body

weight gain, indicating increased qualitative susceptibility in the young, though a clear no-observed-adverse-effect level (NOAEL) was established.

There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies, and imidacloprid was not genotoxic in a variety of assays.

Food Quality Protection Act (FQPA) Decision: The RAB1 risk assessment team recommends that the FQPA Safety Factor (SF) be reduced to 1X for all exposure scenarios, except for the acute dietary endpoint for all populations for which the FQPA SF has been reduced to 3X because of the lack of NOAEL in the critical study selected (rat ACN). This decision was based on the following (see Section 4.6 for more detail):

The existing toxicology database for imidacloprid is adequate for FQPA SF evaluation. The following acceptable studies are available: developmental study in rats and rabbits; 2-generation reproduction study in rats; ACN and subchronic neurotoxicity (SCN) studies in rats; and DNT study in rats.
Evidence of neurotoxicity was observed in the ACN and DNT studies, but not the SCN study or any other studies in the imidacloprid database.
There was increased qualitative susceptibility in the rat DNT study. However, the concern is low because a clear NOAEL was established for the offspring neurotoxic effects and the accompanying maternal food consumption and body weight decrements. Further, there was no evidence of increased susceptibility (quantitative or qualitative) based on the results of the pre-natal developmental toxicity study in rats and rabbits and rat two-generation reproductive toxicity study. Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.
There are no residual uncertainties in the exposure database.

Residue Chemistry and Drinking Water Assessments: The residue chemistry and drinking water databases are adequate to assess potential human exposure to imidacloprid. Adequate residue chemistry data have been submitted to support the proposed use on oyster beds as well as the proposed tolerances on fish and fish, shellfish-mollusc. No residue data have been submitted in support of the proposed Section 18 Emergency Exemption use on sugarcane. However, previously-submitted residue data are adequate to support the proposed use and time-limited tolerances on sugarcane, cane and sugarcane, molasses. EFED provided Tier 1 estimated drinking water concentrations (EDWCs) for surface water [using FQPA Index Reservoir Screening Tool (FIRST)] and groundwater [using Screening Concentration in Ground Water (SCI-GROW)] for imidacloprid and its degradates (imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin).

Dietary (Food and Drinking Water) Exposure Assessment: Acute and chronic dietary (food and drinking water) exposure analyses were conducted for the general U.S. population and various population subgroups using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID; Ver. 3.16). For acute and chronic dietary risk estimates, HED's level of concern (LOC) is for estimates that exceed 100% acute population-adjusted dose (aPAD) or chronic population-adjusted dose (cPAD), respectively. The acute dietary exposure assessment was unrefined (assuming tolerance-level residues and assuming 100% crop treated (CT) for all registered and proposed commodities), and the chronic dietary exposure assessment was partially refined (using tolerance-level residues for all registered and

proposed commodities, and %CT information for some commodities). The results indicate that the acute (95th percentile) and chronic dietary exposure estimates are below HED's LOC for the general U.S. population and all other population subgroups. For both acute and chronic assessments, the most highly exposed population subgroup is children 1-2 years old at 74% of the aPAD and 28% of the cPAD, respectively.

Residential (Non-Occupational) Exposure Assessment: The proposed use of imidacloprid on oyster beds in WA can result in residential exposure via potential contact with residues in oyster-bed water or sediment during recreational swimming. In addition, imidacloprid has several registered uses which may result in residential exposure. Based on these registered use patterns, there is a potential for short-term dermal and inhalation handler; and short-term dermal, inhalation, and incidental oral post-application exposure. There is also the potential for intermediate- and long-term exposures from the pet collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets).

The equations and inputs for the post-application exposures due to the oyster bed use were generally developed from HED's SWIMODEL V 3.0, and using updated body-weight information. All potential residential exposures from existing uses were re-evaluated utilizing the 2012 Residential standard operating procedures (SOPs) and policy changes on body weight. The resulting margins of exposure (MOEs) were all ≥140; and, therefore, do not exceed HED's LOC.

Aggregate Exposure Scenarios and Risk Conclusions: For the proposed uses, human-health aggregate risk assessments have been conducted for the following exposure scenarios: acute aggregate exposure (food + drinking water), short-term aggregate exposure (food + drinking water + residential), and chronic aggregate exposure (food + drinking water + residential). Although there are intermediate-term residential exposures, an intermediate-term aggregate was not quantitatively assessed since (1) the short- and intermediate-term PODs are the same and (2) the short-term aggregate provides a worst-case estimate of residential exposure. For these reasons, the short-term aggregate is protective of the longer-term exposures. A cancer aggregate risk assessment was not performed because there is no evidence that imidacloprid is carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment as a conservative, health-protective measure. All aggregate risk estimates are not of concern to HED for the scenarios listed above.

Occupational Handler and Post-application Exposure Estimates: Occupational short-term dermal and inhalation handler exposures are expected for individuals involved in applications of imidacloprid to oyster beds and sugarcane. For the proposed oyster bed use, HED has determined that risk estimates are not a concern (i.e., MOE >100) with baseline attire and chemical-resistant gloves (as required on the label). For the proposed sugarcane use, HED has determined that risks are not a concern with baseline attire. For aerial applications, no risks of concern were identified for individuals in enclosed cockpits.

For the proposed use of imidacloprid on oyster beds, the extent of post-application exposure is expected to be non-occupational in nature. Thus, any formal occupational post-application dermal or inhalation exposures (e.g., during oyster harvesting) is adequately covered in the residential exposure assessment. Based on the proposed Section 18 Emergency Exemption use of imidacloprid on sugarcane, occupational post-application dermal exposures are expected. The

short-term post-application assessments resulted in MOEs of 100 or greater on "day 0" (immediately after application) for all exposure activities, and are not of concern. The 12-hour restricted entry interval (REI) is adequate for the proposed use patterns.

Review of Human Research: This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1); Agricultural Handler Exposure Task Force (AHETF) database; the Outdoor Residential Exposure Task Force (ORETF) database; and Agricultural Reentry Task Force (ARTF) database, are subject to ethics review pursuant to 40 CFR 26, have received that review, and are compliant with applicable ethics requirements. For certain studies that review may have included review by the Human Studies Review Board. Descriptions of data sources as well as guidance on their use can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html and http://www.epa.gov/pesticides/science/post-app-exposure-data.html.

2.0 HED Recommendations

HED concludes that the toxicological, residue chemistry and occupational/residential databases support a Section 3 registration and establishment of the tolerances listed in Section 2.2.2. In addition, the databases support a Section 18 Emergency Exemption request and the establishment of time-limited tolerances listed in Section 2.2.2. HED is not recommending for any additional data or label modifications in conjunction with this petition.

2.1 Data Deficiencies

No additional data are required to support the proposed use.

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant [Bayer gas chromatography/mass spectrometry (GC/MS) Method 00200] and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method [high-performance liquid chromatography/ultraviolet (HPLC/UV) Method 00357] (Memos, F. Griffith, 18-JUN-1993, D187911; 1-JUN-1994, D202113; 8-JUN-1994, D200233; 8-JUN-1995, D213252; and 18-DEC-1995, D221591).

Bayer Corporation previously submitted adequate multiresidue (MRM) recovery data for imidacloprid and the metabolites 5-hydroxy imidacloprid, imidacloprid olefin, des nitro imidacloprid, and 6-chloronicotinic acid (6-CNA) through Food and Drug Administration (FDA) Protocols A through E (Memos, F. Griffith, 18-JUN-1993, D187911; 15-JUN-1993, D193027; 8-JUN-1994, D200233; and 22-JUN-1994, D194206). Imidacloprid and its metabolites were not recoverable by these methods. The results of the MRM testing for imidacloprid were forwarded

to FDA for inclusion in the Pesticide Analytical Method Volume I (PAM I) (Memo, F. Griffith, 15-JUL-1993, D193005).

2.2.2 Recommended Tolerances

Table 2.2.2. Tolerance Summary for Imidacloprid.

Commodity	Proposed Tolerance (ppm)	Currently Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (*correct commodity definition*)
2E7988 [§180.472(a) General]				
fish	0.05	-	0.05	
fish-shellfish, mollusc	0.05	-	0.05	
12LA11 [§180.472(b) Section 18 emergency exemptions]				
sugarcane, cane	-	-	6.0	
sugarcane, molasses	-	-	50	

2.2.3 Revisions to Petitioned-For Tolerances

PP# 2E7988: The residue chemistry data support the proposed tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on fish at 0.05 ppm, and fish-shellfish, mollusc at 0.05 ppm. No revisions to the proposed tolerances are necessary.

PP#12LA11: The residue chemistry data support the time-limited tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on sugarcane, cane at 6.0 ppm; and sugarcane, molasses at 50 ppm.

2.2.4 International Harmonization

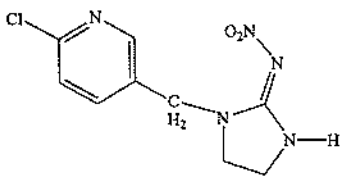
There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for imidacloprid on fish, molluscs, or sugarcane. Therefore, harmonization of MRLs and U.S. tolerances is not an issue at this time.

2.3 Label Recommendations

HED is not recommending for any changes to the Protector® 0.5G (EPA Reg. No. xxx-xxx), and Protector® 2F (EPA Reg. No. xxx-xxx) labels.

3.0 Introduction

3.1 Chemical Identity

Table 3.1. Test Compound Nomenclature.	
Chemical Structure	
Common Name	Imidacloprid
Company Experimental Name	Imidacloprid
IUPAC Name	(*EZ*)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine
CAS Name	1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine
CAS #	138261-41-3
End-use Products (EUP)	Protector® 2F (EPA Reg. No. xxx-xxx) Protector® 0.5G (EPA Reg. No. xxx-xxx)

3.2 Physical/Chemical Characteristics

The physical and chemical properties, as well as a summary of relevant environmental fate parameters are detailed in Appendix B. Imidacloprid has a low vapor pressure (10^{-7} mPa); therefore, it is not a volatile pesticide. The low Henry's law constant ($6.5X10^{-11}$ atm m^3/mole) also indicates that it has a low potential of volatizing from water. Imidacloprid has a low octanol water partition coefficient (0.57); therefore, it is not expected to bioaccumulate in lipophilic matrices. It is highly soluble in water (1.54 g/L), which, coupled with its low octanol water coefficient, suggests a potential to leach to ground water, as well as transport to surface water via runoff. In view of its environmental fate properties including persistence for many months in soil and water, imidacloprid, will translocate throughout treated plants regardless of the method of application.

3.3 Pesticide Use Pattern

PP#2E7988: The petitioner has submitted draft labels for the Protector® 0.5G (EPA Reg. No. xxx-xxx), and Protector® 2F (EPA Reg. No. xxx-xxx). A summary of the proposed use patterns are detailed in Table 3.3.1. The proposed imidacloprid labels direct mixers, loaders, applicators and other handlers to wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. In addition, the label for the granule formulation directs users to wear a dust mask. The proposed label specifies a 12-hour REI.

Table 3.3.1. Summary of Proposed Directions for Use of Imidacloprid on Oyster Beds.

Use Site	Trade Name (EPA Reg. No.)	Application Equipment	App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A)	PHI[1] (days)	Max. # App.	Min. GPA[2]	RTI[3] (days)
Oyster beds	Proteclor® 0.5G (xxxxx-xx)	Drop/rotary spreader; Tractor-drawn spreader; Belly grinder Helicopter	0.5	0.5	30	1	NA	NA
	Protector® 2F (xxxxx-xx)	Groundboom, Helicopter, Backpack	0.5	0.5	30	1	ground: 5 air: 2	

Restrictions:

- Not for sale to any persons other than a member of the Willapa-Greys Harbor Oyster Growers Association.
- A single application/year is allowed.
- No adjuvants or surfactants allowed.
- Aerial applications must be made on beds exposed at low tide.
- Applications from a floating platform or boat may be made under water using a calibrated granular applicator.
- All application must be made between April 15 and December 15. Do not apply aerially during Federal Holidays.
- During aerial applications, all public access areas and public boat launches within ¼ mile radius of bed shall be posted.

1. PHI = pre-harvest interval.
2. GPA = gallons of water per acre.
3. RTI = retreatment interval.

PP#12LA11: LDAF has submitted proposed use directions for the use of imidacloprid on sugarcane in LA. A maximum of 20,000 A can be treated under the requested Crisis Exemption. A summary of the proposed use patterns are detailed in Table 3.3.2. The proposed imidacloprid product labels direct mixers, loaders, applicators and other handlers to wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. In addition, the label for the granule formulation directs users to wear a dust mask. The proposed label specifies a 12-hour REI.

Table 3.3.2. Summary of Proposed Directions for Use of Imidacloprid on Sugarcane in LA.

Use Site	Trade Name (EPA Reg. No.)	Application Equipment	App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A)	Minimum PHI[1] (days)	Max. # App.	Min. GPA[2]	RTI[3] (days)
Sugarcane	Admire® Pro (264-758)	Aerially	0.06-0.08	0.16	36	2	NS	NS

1. PHI = pre-harvest interval. The minimum PHI was provided in an email dated 11/19/12 (personal communication between B. Simoneaux to T. Maignan).
2. GPA = gallons of water per acre.
3. RTI = retreatment interval.

HED Conclusions: The use directions provided by the petitioner are adequate to allow evaluation of the residue data relative to the proposed Section 3 use of imidacloprid on oyster beds to control ghost shrimp, and the proposed Section 18 Emergency Exemption request for the use of imidacloprid on sugarcane in LA.

3.4 Anticipated Exposure Pathways

RD has requested an assessment of human-health risk to support the proposed new use of imidacloprid 1) on oyster beds of Willapa Bay and Grays Harbor in Washington State to control burrowing shrimp, and 2) on sugarcane in LA. Humans may be exposed to imidacloprid in food and drinking water since imidacloprid may be applied directly to growing crops and oyster beds, and applications may result in imidacloprid reaching surface and ground water sources of drinking water. There are numerous registered residential uses of imidacloprid; therefore, human exposure in residential or non-occupational settings may occur. In an occupational setting, applicators may be exposed while handling the pesticide prior to application, as well as during application to oyster beds and sugarcane. In addition, for the proposed use on sugarcane, there is a possibility of post-application dermal exposure to occupational workers when reentering field previously treated with imidacloprid.

The most recent human-health risk assessment for imidacloprid was conducted in 2009 (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406). A human-health Scoping Document in support of Registration Review was also recently conducted (Memo, J. Tyler, 3-DEC-2008; D353984). This risk assessment considers all of the aforementioned exposure pathways based on the proposed new use of imidacloprid, but also considers the existing uses as well, particularly for the dietary and residential exposure assessments.

3.5 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf. As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

4.0 Hazard Characterization and Dose-Response Assessment

4.1 Mode of Action

Imidacloprid is a systemic insecticide effective against the larval, nymphal, and adult insect stages. Its postulated insecticidal mode of action involves inhibition at nicotinic acetylcholine receptors, resulting in nerve function impairment. Some of the toxic effects reported in mammals are also consistent with a neurotoxic mode of action.

4.2 Toxicology Studies Available for Analysis

The toxicological database for imidacloprid is adequate for characterization of its hazard, toxicity endpoint selection, and FQPA consideration. In the most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406), the only toxicity data gap noted was an immunotoxicity study as part of the revised 40 CFR §158 data requirements. Since then, a guideline 28-day rat immunotoxicity study has been submitted and reviewed by the Agency. The results of the study are included in this hazard characterization.

4.3 Absorption, Distribution, Metabolism, & Excretion (ADME)

Following oral administration in the rat, ^{14}C-methylene-radiolabeled imidacloprid was rapidly absorbed with a time to maximum plasma concentration of 1.1 - 2.5 hours post-dose. Absorption was also extensive based on the extent of urinary (70-80% of recovered radioactivity) and biliary (~31.8% based on studies with bile-fistulated animals) excretion of radioactivity. Plasma elimination was biphasic with an estimated primary plasma clearance half-life of 3 hours and a secondary, minor half-life ranging between 26-118 hours. Urine was the primary route of excretion. Total tissue burden after 48 hours was approximately 0.5% of the administered radioactivity. Though retention of radioactivity was minimal, liver, kidney, lung, skin, and plasma showed the highest levels. Other less significant sites of radioactivity were the brain and testes. There were two major routes of biotransformation for imidacloprid. The first included an oxidative cleavage of the parent compound followed by dechlorination to give 6-CNA. The second route included the hydroxylation of imidazolidine. There were no significant differences in ADME processes between sexes or dose levels tested.

4.4 Dermal Absorption

There is *no* dermal absorption study available for imidacloprid. However, a dermal-absorption factor (DAF) of 7.2% has been previously estimated based on the ratio of the maternal lowest-observed-adverse-effect level (LOAEL) of 72 mg/kg bw/day from a rabbit developmental toxicity study and the NOAEL from a dermal-specific toxicity study in rabbits.

4.5 Summary of Toxicological Effects

The main targets of toxicity following oral administration of imidacloprid in mammalian systems were the nervous system and the thyroid. The most sensitive species tested was the rat. Evidence of neurotoxicity was reported in the rat ACN as changes in clinical signs and FOB measurements including decreased motor and locomotor activities, tremors, gait abnormalities, increased righting reflex impairments and body temperature, decreased number of rears and

response to stimuli, and decreases in forelimb and hindlimb grip strength. Also, in a rat DNT study where imidacloprid was administered to pregnant/lactating dams in the diet, there were decreases in offspring motor activity measurements and a small but statistically significant decrease in the caudate/putamen width in the brain of female pups. No neurotoxic effects were reported in any other toxicity study including the rat subchronic neurotoxicity study.

Long-term exposure to imidacloprid resulted in an increased incidence of mineralized particles in the thyroid colloid of rats, body weight decrements in mice, and no toxic effects in dogs. No other thyroid effects were measured in the rat study.

In prenatal developmental toxicity studies in rats and rabbits, there were developmental effects at dose levels that also produced maternal toxicity. In the rat study, there was a slight increase in the incidence of wavy ribs at a dose level higher than that causing deficit in maternal body-weight gain. Developmental effects in the rabbit occurred at the same dose as severe maternal toxicity including deaths and body-weight deficits. Developmental effects in rabbits included abortions, total litter resorptions, increased post-implantation loss due to increased late resorptions, decreased fetal weights, and an increased incidence of wavy ribs in the high-dose group. In the rat two-generation reproductive toxicity study, there were decreases in pup body weights reported in both litters of each generation at the same dose level as parental effects manifested as decreased premating and gestational body-weight gain.

In a recently submitted immunotoxicity study in rats, there were no immunotoxic effects reported at the highest dose level tested. The only treatment-related effects were limited to deficits in body weights and food consumption at the highest dose tested.

No toxic effects were identified at the limit dose of 1000 mg/kg bw/day in a dermal toxicity study in rabbits.

In a rat 4-week inhalation toxicity study, there were *no* effects reported (either portal of entry or systemic) at the highest concentration tested.

There was *no* evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies. The RfD/Peer Review Committee classified imidacloprid as a Group E chemical, "Evidence of non-carcinogenicity for humans," by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice (11/10/1993). There was also no concern for mutagenicity across a host of genotoxicity assays.

4.6 SF for Infants and Children (FQPA SF)

The RAB1 risk assessment team recommends that the FQPA SF be reduced to 1X for all exposure scenarios, except for the acute dietary endpoint for all populations for which the FQPA SF has been reduced to 3X because of the lack of a NOAEL in the critical study (the rat ACN). The rationale is provided below.

4.6.1 Completeness of the Toxicology Database

The existing toxicology database for imidacloprid is complete and adequate for FQPA SF evaluation. The following studies are available for consideration: developmental toxicity studies in rats and rabbits; two-generation reproductive toxicity study in rats; ACN and SCN studies in rats, and DNT study in rats.

4.6.2 Evidence of Neurotoxicity

The neurotoxic potential of imidacloprid has been addressed given its postulated insecticidal neurotoxic mode of action, involving nerve function impairment through inhibition at nicotinic acetylcholine receptors. Evidence of neurotoxicity was observed in the ACN and DNT studies but not the SCN study as previously described in the toxicological effects section of this document. No signs of effects on the nervous system were reported in any other studies in the imidacloprid database.

4.6.3 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

There is no evidence of increased susceptibility (quantitative or qualitative) based on the results of pre-natal developmental toxicity studies in rats and rabbits and the rat two-generation reproductive toxicity study where developmental effects were observed at the same or higher doses than those causing maternal effects. In the rat DNT study, however, there is evidence of increased qualitative susceptibility, but the concern is low since: 1) the effects in pups (body-weight deficits, decreased motor activity, and small decrease in female caudate/putamen width) are well-characterized with a clear maternal NOAEL; 2) the pup effects occurred at the same dose as maternal toxicity (decreased body-weight gain and food consumption); and 3) the doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the DNT study. Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.

4.6.4 Residual Uncertainty in the Exposure Database

The *acute* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

The *chronic* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and % CT data verified by the Biological and Economics Analysis Division (BEAD) for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters, which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.

The residential handler and post-application exposure assessments are based upon the residential SOPs in conjunction with PHED unit exposures. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These

assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid.

4.7 Toxicity Endpoint and Point of Departure Selections

4.7.1 Dose-Response Assessment

Table 4.7.4 summarizes the toxicological doses and endpoints selected for human-health risk assessment.

Acute Dietary Endpoint (all populations): The acute endpoint for all populations (including females of childbearing age) was based on decreased motor and locomotor activity in females in the rat acute neurotoxicity study at the LOAEL of 42 mg/kg/day. An FQPA SF of 3X was retained in the form of a database uncertainty factor (UF) for lack of a NOAEL. The database UF of 3X was judged as adequate (as opposed to 10X) because the effect (decreased motor and locomotor activity) shows a good dose response with minimal change as compared to the control group at the LOAEL of 42 mg/kg/day, and statistical significance was only achieved at the next higher dose of 151 mg/kg/day. Furthermore, the LOAEL of 42 mg/kg/day is comparable to the LOAEL of 55 mg/kg/day for offspring effects (which includes decreased motor activity) in the rat DNT study, and the extrapolated NOAEL of 14 mg/kg/day (42/3 = 14) is comparable to and more protective than the NOAEL of 20 mg/kg/day established in the DNT for offspring effects.

The standard combined UF of 100X is being applied to account for interspecies (10X) and intraspecies (10X) extrapolation. Thus, the acute reference dose (aRfD) and aPAD are equivalent at 0.14 mg/kg/day since the FQPA SF is in the form of a database uncertainty (lack of NOAEL) rather than increased susceptibility in the young.

Chronic Dietary (all populations): This endpoint was based on the increased incidence of mineralized particles in thyroid colloids in male rats at the LOAEL of 16.9 mg/kg/day (NOAEL = 5.7 mg/kg/day) in a combined chronic toxicity/carcinogenicity rat study. The standard combined UF of 100X was applied to account for interspecies (10X) and intraspecies (10X) extrapolation. The FQPA SF was not retained for this exposure scenario since the toxicology database is adequate and there were no residual uncertainties for pre-and or post-natal susceptibility. Thus, the chronic reference dose (cRfD) and cPAD are equivalent at 0.057 mg/kg/day.

Incidental Oral [short (1-30 days) - and intermediate (1-6 months)-term]: This endpoint was based on decreased maternal body-weight gain observed in the rat prenatal developmental toxicity study at the LOAEL of 30 mg/kg/day (NOAEL = 10 mg/kg/day). The NOAEL of 30 mg/kg/day is comparable to the extrapolated NOAEL of 14 mg/kg/day from the rat ACN study also evaluated for this endpoint. An MOE of 100 based on interspecies (10X) and intraspecies (10X) extrapolation is adequate for this scenario.

Incidental Oral [long-term (>6 months)]: This endpoint was based on the increased incidence of mineralized particles in thyroid colloids in male rats at the LOAEL of 16.9 mg/kg/day (NOAEL = 5.7 mg/kg/day) in a combined chronic toxicity/carcinogenicity rat study. The standard combined UF of 100x was applied to account for interspecies (10X) and intraspecies (10X) extrapolation. The FQPA SF was not retained for this exposure scenario since the toxicology

database is complete and there were no residual uncertainties for pre-and or post-natal susceptibility.

Dermal [short (1-30 days) - and intermediate (1-6 months)-term]: This endpoint was based on decreased maternal body-weight gain observed in the rat prenatal developmental toxicity study at the LOAEL of 30 mg/kg/day (NOAEL = 10 mg/kg/day). This point of departure (POD) is higher than the LOAEL of 100 mg/kg/day (NOAEL = 30 mg/kg/day) for developmental effects based on an increase incidence of wavy ribs. Although a 21-day rabbit dermal toxicity study was performed and no toxic effects were observed, such studies are based on non-pregnant adult animals and do not account for potential developmental effects.

A DAF of 7.2% has been previously estimated based on the ratio of the LOAEL of 72 mg/kg/day from a rabbit developmental toxicity study and the NOAEL of 1000 mg/kg/day from a dermal-specific toxicity study in rabbits. An MOE of 100 based on interspecies (10X) and intraspecies (10X) extrapolation is adequate for this scenario.

Dermal [long (>6 months)-term]: Because of the duration of this exposure scenario, this endpoint was based on the chronic toxicity/carcinogenicity study in rats. As noted above, the effects consisted of an increased incidence of mineralized particles in thyroid colloids (postulated reservoirs in the thyroid gland for production and storage of thyroid hormones) in male rats at the LOAEL of 16.9 mg/kg/day (NOAEL = 5.7 mg/kg/day). A DAF of 7.2% was previously estimated for imidacloprid (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406) yielding a dermal-equivalent dose (DED) of ≈ 81 mg/kg/day. An MOE of 100 which includes interspecies (10X) and intraspecies (10X) extrapolation is adequate for this scenario.

Inhalation [short (1-30 days) - and intermediate (1-6 months)-term]: This endpoint was based on decreased maternal body-weight gain observed in the rat prenatal developmental toxicity study at the LOAEL of 30 mg/kg/day (NOAEL = 10 mg/kg/day). This POD is higher than the offspring LOAEL of 100 mg/kg/day (NOAEL = 30 mg/kg/day) based on an increase incidence of wavy ribs. Although a 4-week rat inhalation toxicity study was performed and no toxic effects were observed (no LOAEL identified), such studies are based on non-pregnant adult animals and do not account for potential developmental effects. 100% absorption is being assumed via this route of exposure. An MOE of 100 based on interspecies (10X) and intraspecies (10X) extrapolation is adequate for this scenario.

Inhalation *[long (>6 months)-term]*: Because of the duration of this exposure scenario, this endpoint was based on the chronic toxicity/carcinogenicity study in rats. As noted above, the effects consisted of an increased incidence of mineralized particles in thyroid colloids (postulated reservoirs in the thyroid gland for production and storage of thyroid hormones) in male rats at the LOAEL of 16.9 mg/kg/day (NOAEL = 5.7 mg/kg/day). An MOE of 100 which includes interspecies (10X) and intraspecies (10X) extrapolation is adequate for this scenario.

4.7.2 Recommendation for Combining Routes of Exposure for Risk Assessment

When there are potential occupational and residential exposures to a pesticide, the risk assessment must address exposures from three major sources, oral, dermal and inhalation, and determine whether the individual exposures can be combined if they have the same toxicological effects. For short- and intermediate-exposure, dermal and inhalation exposures can be combined

because the same endpoint (maternal body weight gain deficits) is being used. Similarly, for long-term exposures, oral, dermal and inhalation endpoints can be combined because of the use of the same endpoint (thyroid toxicity) from the rat chronic toxicity study.

4.7.3 Cancer Classification

Imidacloprid has been classified as a Group E chemical, "Evidence of non-carcinogenicity for humans," by the HED RfD/Peer Review Committee (11/10/93).

4.7.4 Summary of Points of Departure and Toxicity Endpoints Used In Human-Health Risk Assessment

Table 4.7.4. Imidacloprid: Summary of Toxicological Endpoints and Points of Departure for Residential Human-Health Risk Assessment.

Exposure Scenario	Dose Used in Risk Assessment, SFs	RfD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	LOAEL = 42 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 3X	aRfD = aPAD = 0.14 mg/kg	Acute neurotoxicity – rat LOAEL = 42 mg/kg/day, based upon the decrease in motor and locomotor activities observed in females.
Chronic Dietary (All populations)	NOAEL = 5.7 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	cRfD = cPAD = 0.057 mg/kg/day	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Incidental Oral [Short- (1-30 days) & Intermediate (1-6 months) terms]	NOAEL = 10 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain.
Incidental Oral [Long-Term (> 6 months)]	NOAEL = 5.7 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Dermal [Short- (1-30 days) & Intermediate (1-6 months) terms]	NOAEL = 10 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X DAF = 7.2%	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain
Dermal [Long-Term (> 6 months)]	NOAEL = 5.7 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X (DAF = 7.2%)	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Inhalation [Short- (1-30 days) & Intermediate (1-6 months) terms]	NOAEL = 10 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X (Assumed 100% absorption)	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain
Long-Term Inhalation (>6 months)	NOAEL = 5.7 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X (Assumed 100% absorption)	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.

Table 4.7.4. Imidacloprid: Summary of Toxicological Endpoints and Points of Departure for Residential Human-Health Risk Assessment.			
Exposure Scenario	**Dose Used in Risk Assessment, SFs**	**RfD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classified as Group E, "Evidence of non-carcinogenicity for humans."		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed-adverse-effect level. LOAEL = lowest-observed-adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

5.0 Dietary Exposure and Risk Assessment

The residue chemistry data submitted in support of the proposed Section 3 use on oyster beds were reviewed by HED in a memo dated 7-MAR-2012 (Memo, J. Tyler; D400189). The EDWCs were provided by EFED (Memo, J. Melendez; 22-JULY-2009). The acute and chronic dietary exposure assessment was completed in a HED memorandum dated 7-MAR-2012 (Memo, J. Tyler; D400187).

5.1 Residues of Concern Summary and Rationale

Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant, cottonseed, field corn, tobacco, ruminants, and poultry have been submitted and reviewed (Memos, F. Griffith, 20-SEP-1993, D185148; 8-JUN-1994, D200233; and 29-FEB-1996, D217632). The results of the aforementioned plant and livestock metabolism studies were presented to the HED Metabolism Assessment Review Committee (MARC) in 1993 (Memo, F. Griffith, 25-JUN-1993, TXR#: 0050886). The nature of imidacloprid residues in plants and livestock is adequately understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472. In a meeting on 18-DEC-2002, the HED MARC recommended that for surface water risk assessment, degradates of concern should be parent and the three degradates: imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin (Memo, J. Tyler, 13-JAN-2003; D287400).

5.2 Food Residue Profile

PP# 2E7988: No magnitude of the residue in fish or nature of the residue in fish studies were submitted in support of the proposed use on oyster beds. However, the registrant recently submitted a waiver request for both studies. The request was presented to the HED Science Advisory Council for Chemistry (ChemSAC) on 23-FEB-2011, and the ChemSAC agreed with the rationale for the waiver (ChemSAC Minutes). Therefore, data demonstrating the magnitude of the residue or nature of the residue in fish are not necessary to support the proposed use on oyster beds. The ChemSAC determined that the proposed tolerance for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on fish at 0.05 ppm is appropriate.

The submitted magnitude of the residue study in oysters was conducted in accordance with OPPTS Guideline 860.1400, and the data are adequate to support the proposed use. Total

residues of imidacloprid were less than limit of quantitation [LOQ, defined as the lowest level of method validation, LLMV (0.05 ppm)] in/on oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G at an application rate of 0.50 lb ai/A; or Mallot 2F® at an application rate of 2.0 lb ai/A. Samples were analyzed for total imidacloprid residues using an acceptable method, and the study is supported by adequate storage stability data. For oysters, the Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedures could not be used to calculate a possible tolerance as residues of imidacloprid were <LOQ in/on all samples of oyster meat. Therefore, the tolerance of 0.05 ppm for fish-shellfish, mollusc is appropriate.

PP#12LA11: No residue chemistry data were submitted in support of the proposed Section 18 Emergency Exemption request for the use of imidacloprid on sugarcane in LA. In connection with this Section 18, time-limited tolerances should be established at 6.0 ppm in or on sugarcane, cane and at 50 ppm for sugarcane, molasses.

The recommended tolerance level of 6.0 ppm for sugarcane, cane is based on the established tolerance level for leaf petioles, subgroup 4B (Memo, Y. Donovan, 23-MAR-1999; D242320). According to current imidacloprid labels, soil-directed application may be made to leaf petioles, subgroup 4B at a maximum application rate of 0.38 lb ai/A, and a minimum PHI of 45 days. The results of previously submitted celery crop field trial study indicate that the highest residue level of imidacloprid on treated celery is 5.62 ppm following a single soil sidedress application at a rate of 0.5 lb ai/A.

In addition, the results of a previously submitted sugarbeet processing study indicate that total residues of imidacloprid do not concentrate in sugar (0.025X), but do concentrate in molasses (8.3X) (Memo, F. Griffith, 16-MAY-1995; D212683). Therefore, a tolerance of 50 ppm (6.0-ppm tolerance x 8.3) is necessary for sugarcane, molasses. A separate tolerance for sugar is not needed; however, a reduction factor of 0.025X was applied to sugarcane, sugar (6.0 ppm x 0.025 = 0.15 ppm) in the acute and chronic dietary exposure assessment.

5.3 Water Residue Profile

EFED provided Tier 1 EDWCs for surface water (using FIRST) and groundwater (using SCI-GROW) for imidacloprid and its degradates (imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin). EDWCs were not provided for the proposed oyster bed use as EFED does not expect any impacts on drinking water from this particular use (personal communication between M. Barrett and C. Smith, 1-NOV-2012). Therefore, the EDWCs provided in 2009 were incorporated used in this risk assessment. The EDWCs in the 2009 memo were calculated based on a maximum application rate of 0.5 lb ai/A/season. The acute and chronic EDWCs in surface water are 36.0 ppb and 17.2 ppb of imidacloprid, based on applications of the chemical to citrus. The SCI-GROW generated groundwater EDWC is 2.09 ppb of imidacloprid.

Table 5.3. Estimated Tier 1 EDWCs of Imidacloprid in Drinking Water.

Drinking Water Source (Model Used)	Use (Rate modeled)	EDWC (ppb)	
Groundwater (SCI-GROW)	Citrus (0.5 lb ai/A)	Acute and Chronic	2.09
Surface water (FIRST		Acute	36.0
		Chronic	17.2

5.4 Dietary Risk Assessment

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the DEEM-FCID (Ver. 3.16), which uses food consumption data from the USDA's NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008.

5.4.1 Description of Residue and Percent Crop Treated Data Used in Dietary Assessment

The acute dietary exposure assessment was unrefined, using tolerance-level residues and assuming 100% CT for all registered and proposed commodities. The chronic dietary exposure assessment was partially refined using tolerance-level residues for all registered and proposed commodities, and % CT information for some commodities. Exposure to drinking water was incorporated directly in the acute and chronic dietary assessments using the acute (peak) and chronic (annual average) concentrations for surface water generated by the FIRST model, respectively.

In a memo dated 2-AUG-2012, the BEAD provided updated estimated % CT information for several commodities (Memo, J. Alsadek, D403995). For the chronic assessment, the following average weighted % CT information was used: almonds: <1%; apples: 30%; artichokes: 5%; avocados: <1%; beans, green: 5%; blueberries: 10%; broccoli: 55%; cabbage: 25%; caneberries: 10%; cantaloupe: 40%; carrots: <1%; cauliflower: 50%; celery: 10%; cherries: 15%; corn (seed treatment): <2.5%; cotton: 5%; cotton (seed treatment): 5%; cucumbers: 5%; dry beans/peas: <1%; eggplant: 60%; filberts (hazelnuts): <2.5%; grapefruit: 25%; grapes: 30%; honeydew: 30%; lemons: 5%; lettuce: 65%; onions: <1%; oranges: 20%; peaches: 5%; peanuts: <1%; pears: 5%; peas, green: <2.5%; pecans: 15%; peppers: 15%; pistachios: <1%; potatoes: 35%; prunes: <1%; pumpkin: 10%; sorghum (seed treatment): 15%; soybeans (seed treatment): 5%; spinach: 20%; squash: 15%; strawberries: 10%; sugar beets: <2.5%; sweet corn: <1%; tangerines: 10%; tobacco: 25%; tomatoes: 25%; walnuts: 5%; watermelon: 20%; wheat (seed treatment): 10%.

5.4.2 Acute Dietary Risk Assessment

An unrefined (using tolerance-level residues and assuming 100% CT for all registered and proposed commodities) acute dietary exposure assessment was conducted for the general U.S. population and various population subgroups. This assessment indicates that the acute dietary exposure estimates are below HED's LOC, <100% aPAD, at the 95th exposure percentile for the general U.S. population and all other population subgroups. The acute dietary exposure is estimated for the U.S. population at 28% of the aPAD and the most highly exposed population subgroup, children 1-2 years old, at 74% of the aPAD. The acute assessment was highly conservative, using several upper-end assumptions. Additional refinements, such as inclusion of anticipated residues (ARs) and %CT data could be made in order to refine the acute assessment. However, HED is confident that the assessment does not underestimate risk to the general U.S. population or any population subgroup.

5.4.3 Chronic Dietary Risk Assessment

A partially refined (using tolerance-level residues for all registered and proposed commodities and %CT data for some commodities) chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. This assessment concludes that

the chronic dietary exposure estimates are below HED's LOC (<100% cPAD) for the general U.S. population and all population subgroups. The chronic dietary exposure is estimated for the U.S. population at 8.3% of the cPAD and the most highly exposed population subgroup, children 1-2 years old, at 28% of the cPAD. Additional refinements, such as inclusion of ARs and % market-share data for the proposed uses could be made in order to refine the chronic assessment. However, HED is confident that the assessment does not underestimate risk to the general U.S. population or any population subgroup.

5.4.4 Summary Table

Table 5.4.4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Imidacloprid.

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.038591	28	0.004707	8.3
All Infants (<1 year old)	0.080374	57	0.007691	13
Children 1-2 years old	0.103801	74*	0.016205	28*
Children 3-5 years old	0.081638	58	0.011274	20
Children 6-12 years old	0.044966	32	0.006225	11
Youth 13-19 years old	0.026992	19	0.003594	6.3
Adults 20-49 years old	0.025911	18	0.003754	6.6
Adults 50-99 years old	0.025662	18	0.003812	6.7
Females 13-49 years old	0.025875	18	0.003725	6.5

*The subpopulation(s) with the highest risk estimates.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

The proposed use of imidacloprid on oyster beds in Washington State's Willapa Bay and Grays Harbor is not expected to result in residential handler exposure (professionally applied), but can result in residential post-application exposures via potential contact with residues in the oyster bed water or sediment during recreational swimming, or in the case of subsistence fishermen or local Native American tribes, collecting oysters. These scenarios are consistent with the human-health risk assessment for an identical use pattern – applications of carbaryl to control burrowing shrimp in Willapa Bay and Grays Harbor (Memo, J. Dawson, 14-MAR-2003: D287532). There are no residential uses associated with the proposed Section 18 Emergency Exemption use on sugarcane.

For the purposes of evaluating aggregate (dietary and non-dietary) exposure for the proposed uses, imidacloprid has a variety of existing residential uses that should be considered, including residential lawns and gardens, indoor uses for bed bugs and crack-and-crevice treatments, pet uses (spot-on treatment and collars), and pre- and post-construction termiticide and wood preservative uses. Short-term dermal and inhalation handler exposures are expected. Generally, short-term dermal, inhalation, and incidental oral post-application exposures are expected, with the exception of intermediate- and long-term exposures from the pet collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets). Risks from these uses have been re-evaluated to reflect updates to HED's 2012 Residential SOPs (http://www.epa.gov/pesticides/science/residential-exposure-sop.html) along with policy changes for body weight assumptions. The revision of residential exposures will impact the human health aggregate risk assessment for imidacloprid.

The registered and proposed residential uses were evaluated by HED and reviewed by the HED Science Advisory Council for Exposure (ExpoSAC; Memo, M. Crowley, 6-MAR-2012, D400191).

6.1 Residential Handler Exposure and Risk Estimates

HED uses the term "handlers" to describe those individuals who are involved in the pesticide application process. As the new use is expected to be professionally applied, residential handler exposure is not expected. For exposure to professional applicators as a result of the new use, see Section 9.1.

Unlike the proposed uses, however, existing residential uses, considered for the purposes of the aggregate risk assessment, are expected to result in residential handler exposure. HED believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. Residential handlers are addressed somewhat differently by HED than occupational pesticide applicators as homeowners are assumed to complete all elements of an application without use of any protective equipment.

Risks from these uses have been estimated in past human-health risk assessments; however, have been re-evaluated to reflect updates to HED's 2012 Residential SOPs and policy changes for body weight assumptions. The quantitative exposure/risk assessment developed for residential handlers for existing imidacloprid uses is based on the following scenarios:

- Mixing/loading/applying liquid formulations for use with manually-pressurized handwands in indoor settings (bed-bug treatments and crack-and-crevice treatments);
- Mixing/loading/applying liquid formulations for use with hose-end sprayers on lawns and gardens;
- Mixing/loading/applying liquid formulations for use with a bucket or watering can to treat plant stems and tree trunks;
- Applications to gardens using a ready-to-use (RTU) trigger-spray bottle;
- Loading/applying granule formulations to lawns and gardens using a push-type/rotary spreader;
- Applications of potting spikes and potting mediums to garden plants; and,
- Applications of spot-on treatments and collars to pets.

HED expects the duration of exposure for residential handlers to be short-term (1-30 days) in duration. Assessing exposures and risks resulting from residential uses is very similar to assessing occupational exposures and risks, except that a tiered approach for personal protection using increasing levels of personal-protective equipment (PPE) is not used in residential handler risk assessments. Homeowner handler assessments are based on the assumption that individuals are wearing shorts, short-sleeved shirts, socks, and shoes.

Table 6.1 below provides a summary of residential handler risk estimates from existing residential uses of imidacloprid, updated using the 2012 Residential SOPs and policy changes for body weigh assumptions. Short-term risk estimates for residential handlers are not of concern (MOEs >100).

Table 6.1. Residential Handler Non-cancer Exposure and Risk Estimates for Existing Residential Uses of Imidacloprid.

Exposure Scenario		MOE Level of Concern	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Maximum Application Rate[1]	Area Treated or Amount Handled Daily[2]	Dermal		Inhalation		Total
							Dose (mg/kg/day)[3]	MOE[4]	Dose (mg/kg/day)[5]	MOE[6]	MOE[7]
Indoors (bed bug and crack-and-crevice treatments)		100	69	1.1	0.008 lb ai/gallon	0.5 gallons	0.00025	40,000	5.5E-05	180,000	33,000
Gardens /Trees	Hose-end sprayer	100	58	0.0014	0.5 lb ai/acre	1200 ft^2	0.00072	14,000	2.4E-07	41,000,000	14,000
	Walering can	100	58	0.0014	0.25 lb ai/gallon	1 gallon	0.013	770	4.4E-06	2,300,000	770
	Potting medium	100	160	0.38	0.00288 lb ai/container	1 container	0.00041	24,000	1.4E-05	730,000	23,000
	Potting spikes	100	160	0.38	0.00011 lb ai/spike	10 spikes	0.00016	63,000	5.2E-06	1,900,000	61,000
	Trigger-spray bottle	100	85.1	0.061	0.000189 lb ai/bottle	2 bottles	0.000029	350,000	2.9E-07	35,000,000	340,000
	Rotary spreader	100	0.81	0.0026	0.4 lb ai/acre	1200 ft^2	0.000008	1,200,000	3.6E-07	28,000,000	1,200,000
Pets	Spot-on	100	120	Negligible	0.001 lb ai/pet	2 pets	0.00022	46,000	NA	NA	NA
	Collar	100	120	Negligible	0.0099 lb ai/pet	2 pets	0.0021	4,700	NA	NA	NA
Lawns /Turf	Hose-end sprayer	100	13.4	0.022	0.5 lb ai/acre	0.5 acres	0.003	3,300	6.9E-05	150,000	3,200
	Rotary spreader	100	0.81	0.0026	0.4 lb ai/acre	0.5 acres	0.00015	69,000	6.5E-06	1,500,000	66,000

[1] See Table 4.2 for assessment reference.
[2] Based on 2012 Residential SOPs. Departures from the SOP include the gardens/trees: watering-can scenario (per label, 1 gallon of solution treats 20 trees), the potting-medium scenario (per label, 1 container = 20 lbs), and the potting-spike scenario (10 spikes considered a reasonable use estimate).
[3] Dermal Dose = Dermal Unit Exposure (mg/lb ai) x Application Rate (lb ai/acre or gal) x Area Treated or Amount Handled (A or gallons/day) x DAF (%) / BW (kg).
[4] Dermal MOE = Dermal NOAEL (mg/kg/day) / Dermal Dose (mg/kg/day).
[5] Inhalation Dose = Inhalation Unit Exposure (mg/lb ai) x Conversion Factor (0.001 mg/ug) x Application Rate (lb ai/acre or gal) x Area Treated or Amount Handled (A or gallons/day) / BW (kg).
[6] Inhalation MOE = Inhalation NOAEL (mg/kg/day) / Inhalation Dose (mg/kg/day).
[7] Total MOE = NOAEL (mg/kg/day) / (Dermal Dose + Inhalation Dose) OR Total MOE = 1 / [(1/Dermal MOE) + (1/Inhalation MOE)].

6.2 Post-Application Exposure and Risk Estimates

As a result of both the proposed use on oyster beds and from existing residential uses, there is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with imidacloprid.

Based on the proposed use pattern, only short-term post-application dermal, incidental oral, and inhalation exposures to imidacloprid residues in oyster bed water and sediment are expected. This assessment mimics those scenarios reviewed for an identical use pattern for the ai carbaryl (Memo, J. Dawson, 14-MAR-2003; D287532). The equations and inputs are generally derived from SWIMODEL 3.0, developed by EPA as a screening tool to conduct exposure assessments of pesticides found in swimming pools and spas and EPA's Risk Assessment Guidance for Superfund – Part E, Supplemental Guidance for Dermal Risk Assessment ("RAGS-E").

For the registered residential uses, in general, short-term dermal, inhalation, and incidental oral post-application exposures are expected. Intermediate- and long-term dermal, incidental oral and inhalation exposures are expected from the pet collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets). These risks were estimated in previous assessments (listed below, where applicable) but have been re-evaluated here using the updated 2012 Residential SOPs and policy changes for body weight assumptions.

The quantitative exposure/risk assessment for residential post-application exposure is based on the following scenarios:

- As a result of the proposed use to control burrowing shrimp in Washington State's Willapa Bay and Grays Harbor intertidal oyster beds:
  - Ingestion of water during recreational swimming (both adults and children 3<6 years old);
  - Dermal exposure during recreational swimming (both adults and children 3<6 years old);
  - Dermal exposure to oyster bed sediment while collecting/harvesting oysters (adults) and playing (children 3<6 years old);
  - Inhalation exposure during recreational swimming and/or collecting/harvesting oysters (both adults and children 3<6 years old); and,
  - Incidental ingestion of sediment via hand-to-mouth activities (children 3<6 years old only).

- As a result of existing residential uses:
  - Dermal exposure from contact with treated turf (both adults and children 11<16, 6<11, and 1<2 years old) – updated from most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406);
  - Dermal exposure from contact with treated gardens and trees (adults and children 6<11 years old) – updated from most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406);

- Dermal exposure from contact with treated mattresses (bed-bug treatments) and indoor surfaces (both adults and children 1<2 years old) – updated from most recent risk assessment (Memo, K. Lowe, 17-FEB-2009; D367396);
- Dermal exposure from contact with treated pets (both adults and children 1<2 years old) – updated from most recent risk assessments (Memos, G. Kramer *et al.*, 16-MAR-2009, D375406 (spot-on); K. Lowe, 17-FEB-2009; D367396 (collar));
- Dermal exposure from contact with treated wood (both adults and children 1<2 years old) – updated from most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406);
- Inhalation exposure following mattress treatments and indoor crack-and-crevice treatments (both adults and children 1<2 years old) – updated from most recent risk assessment (Memo, K. Lowe, 17-FEB-2009; D367396);
- Incidental ingestion from contact with treated turf (children 1<2 years old only) – updated from most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406);
- Incidental ingestion from contact with treated indoor surfaces (children 1<2 years old only) – updated from most recent risk assessment (Memo, K. Lowe, 17-FEB-2009; D367396);
- Incidental ingestion from contact with treated pets (children 1<2 years old only) – updated from most recent risk assessments (Memos, G. Kramer *et al.*, 16-MAR-2009, D375406 (spot-on); K. Lowe, 17-FEB-2009; D367396 (collar)); and,
- Incidental ingestion from contact with treated wood (children 1<2 years old only) – updated from most recent risk assessment (Memo, G. Kramer *et al.*, 16-MAR-2009; D375406).

The lifestages (e.g., adults, children 1<2 years old, etc.) selected for each post-application scenario as a result of the registered uses are based on an analysis provided as Appendix A in the 2012 Residential SOPs. The lifestages (adults and children 3<6 years old) selected for the post-application scenarios as a result of the proposed oyster bed use are based on the expected potential for individuals to be in oyster beds and the activities they will conduct. In the case of Native American tribes and subsistence fishermen, it could be the case that families participate in these activities; thus, young children are considered as well. These lifestages are not the only lifestages that could be potentially exposed for these post-application scenarios; however, the assessment of these lifestages is health protective for the exposures and risk estimates for any other potentially exposed lifestages.

Table 6.2.1 below provides a summary of residential post-application risk estimates from the proposed use of imidacloprid on oyster beds. Table 6.2.2 below provides a summary of residential post-application risk estimates from existing residential uses of imidacloprid, updated using the 2012 Residential SOPs and policy changes for body weight assumptions.

Table 6.2.1. Residential Post-application Non-cancer Exposure and Risk Estimates from the Proposed Use of Imidacloprid to Control Burrowing Shrimp.[1]

Use/Target	Lifestage	Post-application Exposure Scenario		Dose (mg/kg-day)	MOE	Combined Routes (X indicates included in Combined MOE)	Combined MOE
WA State Willapa Bay and Grays Harbor Intertidal Oyster Beds	Adult	Dermal (water)	Swimming	5.6E-06	1,800,000	X	59,000
		Dermal (sediment)	Oyster Harvesting	1.2E-04	85,000	X	
		Ingestion (water)		4.5E-05	220,000	X	
		Inhalation		3.7E-09	2,700,000,000	X	
	Children 3<6 years	Dermal (water)	Swimming	7.3E-06	1,400,000	X	2,600
		Dermal (sediment)	Playing in oyster bed	2.4E-03	4,200	X	
		Ingestion (water)		3.5E-04	28,000	X	
		Hand to Mouth (sediment)		1.1E-03	8,800	X	
		Inhalation		8.2E-09	1,200,000,000	X	

[1] All MOEs represent short-term risk estimates. Intermediate- and long-term exposures are not expected from this use.

Table 6.2.2. Residential Post-application Non-cancer Exposure and Risk Estimates for Existing Residential Uses of Imidacloprid.[1]

Use/Target		Lifestage	Post-application Exposure Scenario		Dose (mg/kg-day)	MOE[5]	Combined Routes (X indicates included in Combined MOE)	Combined MOE
Turf (spray application)[2]		Adult	Dermal	High-contact (playing)	0.014	740	--	NA
				Mowing	0.00026	36,000	--	
				Golfing	0.0011	9,400	--	
		Child 11<16	Dermal	Mowing	0.00032	32,000	--	NA
				Golfing	0.0012	8,100	--	
		Child 6<11	Dermal	Golfing	0.0015	6,900	--	NA
		Child 1<2	Dermal (high-contact play)		0.027	370	X	290
			Hand to Mouth		0.0076	1,300	X	
			Object to Mouth		0.00023	43,000	--	
			Incidental Soil Ingestion		1.7E-05	590,000	--	
Gardens/ Trees (spray application)[2]		Adult	Dermal		0.023	430	--	NA
		Child 6<11	Dermal		0.016	630	--	NA
Indoor	Bed bug (mattress)	Adult	Dermal		0.00059	17,000	--	NA
		Child 1<2	Dermal		0.0013	7,400	--	NA
	Crack-and-crevice	Adult	Dermal (playing on carpet)[3]		0.00088	11,000	X	6,200
			Inhalation		0.0007	14,000	X	
		Child 1<2	Dermal (playing on carpet)[3]		0.00085	12,000	X	1,800
			Inhalation		0.003	3,400	X	
			Hand to Mouth (playing on carpet)[3]		0.0018	5,700	X	

Table 6.2.2. Residential Post-application Non-cancer Exposure and Risk Estimates for Existing Residential Uses of Imidacloprid.[1]

Use/Target		Lifestage	Post-application Exposure Scenario		Dose (mg/kg-day)	MOE[5]	Combined Routes (X indicates included in Combined MOE)	Combined MOE
Pets	Spot-on	Adult	Dermal (playing with small cat)[4]		0.0055	1,800	--	NA
		Child 1<2	Dermal (playing with small cat)		0.0139	720	X	630
			Hand to Mouth (playing with small cat)[4]		0.0019	5,200	X	
	Collar	Adult	ST/IT	Dermal (playing with small cat)[4]	0.0028	3600	--	NA
			LT	Dermal (playing with small cat)[4]	0.0028	2000	--	NA
		Child 1<2	ST/IT	Dermal (playing with small cat)[4]	0.0071	1,400	X	1,200
				Hand to Mouth (playing with small cat)[4]	0.00098	10,000	X	
			LT	Dermal (playing with small cat)[4]	0.0071	800	X	700
				Hand to Mouth (playing with small cat)[4]	0.00098	5,800	X	
Wood Preservative / Termiticide		Adult	Dermal (playing on deck)		0.0184	540	--	NA
		Child 1<2	Dermal (playing on deck)		0.042	240	X	140
			Hand to Mouth (playing on deck)		0.028	360	X	

[1] See Appendix A for calculations and inputs.
[2] Risk estimates presented only in this table for spray applications, as risks from uses of granule formulations are lower.
[3] Risk estimates presented only in this table from contacting treated carpets, as risks from contacting other surfaces are lower.
[4] Risk estimates presented only in this table from contacting small cats, as risks from other treated pets are lower.
[5] MOEs are for short-term exposures only except for the pet collar which presents risks for short-/intermediate-term (ST/IT) and long-term (LT) exposures.

6.3 Combined Residential Risk Estimates (Multiple Exposure Scenarios)

Because of the potential likelihood for some uses to occur on the same day or over the same exposure duration, risks from some imidacloprid residential uses are combined to determine whether their co-occurrence presents a risk of concern. Residential handler and post-application scenarios are generally not combined. Although there is potential for the same individual (i.e., adult) to apply a pesticide in and around the home and be exposed by reentering a treated area in the same day, this is an unlikely exposure scenario, especially day after day for up to 30 days. Combining both of these exposure scenarios would also be inappropriate because of the conservative nature of each individual assessment.

There may be post-application residential exposure scenarios for a particular pesticide which could be combined for purposes of an aggregate exposure assessment. For imidacloprid, the

outdoor treatments of lawns and gardens have a reasonable probability of co-occurring as do the indoor bed-bug and crack-and-crevice treatments. The likelihood of any of the existing residential uses to co-occur with exposures from the proposed oyster bed use is low, thus risk estimates are not presented. Table 6.3 presents combined risks for these scenarios, using a similar equation as shown in Section 6.2.1 and 6.2.2.

Table 6.3. Non-Cancer Residential Combined (Multiple Exposure Scenarios) Exposure and Risk Estimates for Imidacloprid.

Combined Exposure Scenario	Lifestage	Exposure Scenario	Route of Exposure	Dose	Combined Total Dose (mg/kg-day)	Combined Total MOEs
Outdoor Scenario (Turf/Garden)	Adult	Handler: Turf - Sprays	Dermal	0.003	0.016	620
			Inhalation	6.9E-05		
		Handler: Garden - Sprays	Dermal	0.013		
			Inhalation	4.4E-06		
	Adult	Post-application: Turf - Sprays	Dermal	0.014	0.037	270
		Post-application: Garden - Sprays	Dermal	0.023		
Bedbug Scenario	Adult	Post-application: Perimeter	Dermal	0.00088	0.0022	4,500
		Post-application: Mattress	Dermal	0.00059		
		Post-application: Perimeter/Mattress	Inhalation	0.0007		
	Child	Post-application: Perimeter	Dermal	0.00085	0.0069	1,500
			Hand to Mouth	0.0018		
		Post-application: Mattress	Dermal	0.0013		
		Post-application: Perimeter/Mattress	Inhalation	0.003		

6.4 Residential Risk Estimates for Use in Aggregate Assessment

The residential scenarios listed below should be used for the aggregate (dietary + non-dietary) assessment. Table 6.4 presents the risk estimates.

- The recommended residential exposure for use in the short-term adult aggregate assessment reflects combined dermal post-application exposures from contacting treated lawns and gardens. For the long-term adult aggregate assessment, the recommended residential exposure scenario is contacting treated pets following applications of pet collars.
- The recommended residential exposure for use in the short-term children 1<2 years old aggregate assessment reflects combined dermal and hand-to-mouth exposures from contacting treated wood surfaces (e.g., playing on decks). For the long-term children 1<2 years old aggregate assessment, the recommended residential exposure scenario is contacting treated pets following application of pet collars.

Table 6.4. Recommendations for the Residential Exposures for the Imidacloprid Aggregate Assessment.[1]									
Lifestage	Handler Exposure (mg/kg/day)[2]		Residential Handler Total Exposure (mg/kg/day)[3]	Residential Handler Total MOE	Post-application Exposure (mg/kg/day)[4]			Residential Post-application Total Exposure (mg/kg/day)	Residential Post-application MOE[5]
	Dermal	Inhalation			Dermal	Inhalation	Oral		
Short-/Intermediate-Term									
Adult	0.016	0.0001	0.016	620	0.037	N/A	N/A	0.037	270
Child 1<2	N/A	N/A	N/A	N/A	0.042	N/A	0.028	0.07	140
Long-Term									
Adult	N/A	N/A	N/A	N/A	0.0028	N/A	N/A	0.0028	2,000
Child 1<2	N/A	N/A	N/A	N/A	0.0071	N/A	0.00098	0.0081	700

[1] Bolded risk estimates should contribute to the residential exposure portion of the aggregate assessment.
[2] Handler exposure is the combined lawn and garden uses presented in Section 5.3 – this was the handler scenario with the highest exposures.
[3] For adults, residential total exposure combines the highest dermal and inhalation exposures (Table 5.1.1, 5.2.1, 5.2.2, and 5.2.3), where applicable. For children, total residential exposure combines high-end post application incidental oral AND dermal exposure, where applicable (Table 5.2.1, 5.2.2, 5.3.1).
[4] Total MOE = 1 / (1/Dermal MOE) + (1/Inhalation MOE).
[5] Post-application exposure represents high-end dermal, inhalation and/or incidental oral exposure for the relevant exposure duration.
[6] Total MOE = 1 / (1/Dermal MOE) + (1/Inhalation MOE) + (1/Incidental oral MOE).

6.5 Residential Bystander Post-application Inhalation Exposure

Post-application inhalation exposure while swimming in intertidal oyster beds was assessed for the proposed use of imidacloprid. However, bystander inhalation exposure was not assessed for the existing agricultural uses of imidacloprid. Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed at this time primarily because of the low acute inhalation toxicity (Toxicity Category IV) and low vapor pressure (4×10^{-7} mmHg). However, volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency is in the process of evaluating the SAP report and may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are developed, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for the existing uses of imidacloprid.

6.6 Spray Drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for imidacloprid. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, and State Lead Agencies for pesticide regulation and other parties to develop the best spray-drift-management practices (see the Agency's Spray Drift website for more information at http://www.epa.gov/opp00001/factsheets/spraydrift.htm). The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT® computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray-drift-management practices to reduce off-target drift with specific products with significant risks associated with drift.

Note that an application rate of 0.5 lb ai/A was used in the updated assessment of the existing lawn/turf registration to estimate post-application residential exposure of children. As this rate is equal to or higher than the registered and proposed uses, the exposures resulting from direct application to lawns/turf are likely protective of any exposure via spray drift from the proposed oyster-bed use.

7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative

estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure. In the case of imidacloprid, aggregate risk assessments were performed for acute aggregate exposure (food + drinking water), short-term aggregate exposure (food + drinking water + residential), and chronic aggregate exposure (food + drinking water + residential). Although there are intermediate-term residential exposures, an intermediate-term aggregate was not quantitatively assessed since (1) the short- and intermediate-term points of departure are the same and (2) the short-term aggregate represents worst-case residential exposures. For these reasons, the short-term aggregate is protective of the longer-term exposures. A cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment.

7.1 Acute Aggregate Risk

The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of imidacloprid (food and drinking water). The dermal, inhalation, and incidental oral exposures resulting from short-term residential applications are assessed separately. The acute dietary exposure estimates are below HED's LOC (<100% aPAD) at the 95th exposure percentile for the general U.S. population (28% of the aPAD) and all other population subgroups (see Table 5.4.4). The most highly-exposed population subgroup is children 1-2 years old, at 74% of the aPAD. Therefore, the acute aggregate risk associated with the proposed use of imidacloprid does not exceed HED's LOC for the general U.S. population or any population subgroups.

7.2 Short-Term Aggregate Risk

The short-term aggregate risk assessment estimates risks likely to result from 1- to 30-day exposures to imidacloprid residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used, and average values are used for food and drinking water exposures.

Short-term aggregate risk assessments are necessary for both adults and children as there is potential for both short-term dermal and inhalation handler exposure, and short-term post-application exposure from the residential uses of imidacloprid. For the short-term aggregate risk assessment, potential residential post-application exposures were combined with food and drinking water exposures.

For adults, the combined dermal post-application exposures from contacting treated lawns and gardens resulted in the highest short-term exposure (exposure = 0.037 mg/kg/day; MOE = 270 see Table 6.4). For children, the combined dermal and hand-to-mouth exposure from contacting treated wood surfaces resulted in the highest short-term exposure (exposure= 0.07 mg/kg/day, MOE = 140; see Table 6.4). Therefore, these short-term exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the general U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure) (see Table 5.4.4). As the short-term aggregate MOEs are greater than 100, risks are not of concern.

Table 7.2. Short-Term Aggregate Risk Calculations.

Population	NOAEL (mg/kg/day)	LOC[1]	Max Allowable Exposure[2] (mg/kg/day)	Average Food and Drinking Water Exposure (mg/kg/day)[3]	Residential Exposure (mg/kg/day)[4]	Total Exposure (mg/kg/day)[5]	Aggregate MOE (food, water, and residential)[6]
Adults	10	100	0.1	0.004707	0.037	0.041707	240
Children 1-2 years old	10	100	0.1	0.016205	0.07	0.086205	120

[1] The level of concern (target MOE) includes 10X for interspecies extrapolation and 10X for intraspecies variation.
[2] Maximum Exposure (mg/kg/day) = NOAEL/LOC.
[3] Avg. Dietary Exposure. See Table 5.4.4.
[4] Residential Exposure = Dermal exposure for adults and Oral + Dermal exposure for children.. See Table 6.4.
[5] Total exposure = Avg. Dietary Exposure + Residential Exposure.
[6] Aggregate MOE = NOAEL ÷ Total Exposure.

7.3 Intermediate-Term Aggregate Risk

The intermediate-term aggregate risk assessment estimates risks likely to result from 30 days to 6 months exposure to imidacloprid residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used, and average values are used for food and drinking water exposures.

Although there is potential for intermediate-term residential exposure from the registered pet collar use, an intermediate-term aggregate assessment is not required. The short- and intermediate-term toxicological endpoints are the same, and the exposures assessed in the short-term aggregate (adults- combined dermal post-application exposures from contacting treated lawns and gardens; and children - combined dermal and hand-to-mouth from contacting treated wood surfaces) provide a worst-case estimate of short-term residential exposure. Therefore, the estimates of risk for short-term duration exposures are protective of those for intermediate-term duration exposures.

7.4 Chronic Aggregate Risk

The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of imidacloprid (food and drinking water) and long-term residential uses. High-end estimates of residential exposure are used, and average values are used for food and drinking water exposures.

Based on the proposed and existing use patterns, there is potential for long-term residential exposure from the pet-collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets). For adults, the dermal post-application exposure from contacting treated pets resulted in a long-term exposure of 0.0028 mg/kg/day (MOE = 2,000; see Table 6.4). For children, the combined dermal and hand-to-mouth from contacting treated pets resulted in a combined long-term exposure of 0.0081 mg/kg/day (MOE = 700; see Table 6.4). Therefore, these long-term exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of chronic aggregate risk for the general U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure) (see Table 7.4). As the chronic aggregate MOEs are greater than 100, risks are not of concern.

Table 7.4. Chronic Aggregate Risk Calculations.							
	Chronic/Long-Term Scenario						
Population	NOAEL (mg/kg/day)	LOC[1]	Max Allowable Exposure[2] (mg/kg/day)	Average Food and Drinking Water Exposure (mg/kg/day)[3]	Residential Exposure (mg/kg/day)[4]	Total Exposure (mg/kg/day)[5]	Aggregate MOE (food, water, and residential)[6]
Adults	5.7	100	0.057	0.004707	0.0028	0.007507	760
Children 1-2 years old	5.7	100	0.057	0.016205	0.0081	0.024305	230

[1] The level of concern (target MOE) includes 10X for interspecies extrapolation and 10X for intraspecies variation.
[2] Maximum Allowable Exposure (mg/kg/day) = NOAEL/LOC.
[3] Avg. Dietary Exposure. See Table 5.4.4.
[4] Residential Exposure = Dermal exposure for adults and Oral + Dermal exposure for children. See Table 6.4.
[5] Total exposure = Avg. Dietary Exposure + Residential Exposure.
[6] Aggregate MOE = NOAEL ÷ Total Exposure.

8.0 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to imidacloprid and any other substances and imidacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

9.0 Occupational Exposure/Risk Characterization

Based on the proposed application scenarios and toxicological considerations, non-cancer occupational handler (dermal and inhalation) assessments were conducted for the proposed uses on oyster beds and sugarcane; and occupational post-application (dermal) assessments were conducted for the proposed sugarcane use. The proposed Section 3 use on oyster beds and Section 18 Emergency Exemption use on sugarcane were evaluated by HED and were reviewed by the HED ExpoSAC (Memo, M. Crowley, 6-MAR-2012, D400191; and J. Tyler, 7-MAR-2012; D407182).

9.1 Handler Exposure and Risk Estimates

HED uses the term handlers to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Based on the anticipated use patterns, potential occupational handler exposure scenarios include:

- As a result of the proposed Section 3 use on oyster beds:
  - Mixing/loading the liquid formulation to support aerial and groundboom applications;
  - Mixing/loading the granule formulation to support aerial and tractor-drawn spreader applications;
  - Applications of the granule and diluted liquid formulation using aerial equipment;
  - Applications of the diluted liquid formulation with groundboom sprayers;
  - Applications of the granule formulation using tractor-drawn spreaders;
  - Flagging for aerial applicattons of the granule and diluted liquid formulation;
  - Mixing/loading/applying the liquid formulation with a backpack sprayer; and,
  - Loading/applying the granule formulation with a belly grinder or rotary spreader.

- As a result of use on the proposed Section 18 Emergency Exemption on sugarcane:

  - Mixing/loading liquids to support aerial applications,
  - Applying liquids with enclosed cockpit aerial equipment, and
  - Flagging to support aerial applications.

For the proposed use of imidacloprid to control burrowing shrimp, only short-term exposures are expected due to the limited geographical area of the applications (Willapa Bay and Grays Harbor in Washington State) and the limit of one application per acre per year. As a result, it is unlikely that an individual would make repeated daily applications for 1-6 months for this use. Short-term exposure is also anticipated for the proposed sugarcane use as the use directions limit application to 2 per crop cycle. However, the short- and intermediate-term toxicological endpoints are the same; therefore, the estimates of risk for short-term duration exposures are protective of those for intermediate-term duration exposures. Long-term exposures are not expected; therefore, a long-term assessment was not conducted. The average adult body weight of 80 kg was used for estimating dermal and inhalation doses.

No chemical-specific handler exposure data were submitted in support of this Section 3 registration. It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include PHED 1.1, the AHETF database, the ORETF database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as "unit exposures," are outlined in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (http://www.epa.gov/opp00001/science/handler-exposure-table.pdf), which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html.

Occupational handler exposure assessments are completed by HED using different levels of risk mitigation. Typically, HED uses a tiered approach. The lowest tier is designed as the "baseline"

exposure scenario (i.e., long-sleeve shirt, long pants, shoes, socks, no respirator). If risk estimates are of concern at baseline attire, then increasing levels of PPE (i.e., gloves, respirators) are evaluated. If risk estimates remain a concern with maximum PPE, then engineering controls (i.e., enclosed cabs or cockpits, water-soluble packaging, and closed mixing/loading systems) are evaluated. This approach is used to ensure that the lowest level of risk mitigation that provides adequate protection is selected, since the addition of PPE and engineering controls involves an additional expense to the user and (in the case of PPE) also involves an additional burden to the user due to decreased comfort and dexterity and increased heat stress and respiratory stress. The proposed imidacloprid product labels direct mixers, loaders, applicators and other handlers to wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. In addition, the label for the granule formulation directs users to wear a dust mask.

PP#2E7988: Table 9.1.1 provides a summary of the estimated exposures and risks to occupational pesticide handlers resulting from the use on oyster beds. All dermal and inhalation risk estimates for occupational handlers are above the LOC (MOEs >100) with baseline protection (i.e., long-sleeve shirt, long pants, shoes, and socks) and chemical-resistant gloves. Only engineering control data (i.e., enclosed cockpits) are available for aerial application scenarios. All dermal and inhalation risk estimates for occupational aerial applicators are above the LOC (MOEs >100) with baseline clothing and enclosed cockpits.

PP#12LA11: Table 9.1.2 provides a summary of the estimated exposures and risks to occupational pesticide handlers resulting from the use on sugarcane. For the scenarios where baseline data are available, all dermal and inhalation risk estimates for occupational handlers are above the LOC (MOEs >100) with baseline protection (i.e., long-sleeve shirt, long pants, shoes, and socks). Only engineering control data (i.e., enclosed cockpits) are available for aerial application scenarios. All dermal and inhalation risk estimates for occupational aerial applicators are above the LOC (MOEs >100) with baseline clothing and enclosed cockpits.

The Agency has evaluated scenarios that may be limited in nature such as flagging during aerial applications because engineering controls (i.e., Global Positioning Satellite technology) are now predominantly used as indicated by the 1998 National Agricultural Aviation Association (NAAA) survey of their membership. It appears, however, flaggers are still used in approximately 10-15% of aerial application operations. In cases like these, the Agency strongly encourages the use of the engineering control system but will continue to evaluate risks for flaggers and any other population where a clear exposure pathway exists until the potential for exposure is eliminated. The Agency is aware that NAAA is conducting another survey on exposure issues and will consider those results as are timely and appropriate.

Table 9.1.1. Short-Term Occupational Exposure and Risk Estimates for Imidacloprid Applications to WA Oyster Beds.

Exposure Scenario		Dermal Unit Exposure (ug/lb ai)[1] Mitigation Level	Inhalation Unit Exposure (ug/lb ai)[1] Mitigation Level	Maximum Application Rate[2]	Area Treated or Amount Handled Daily[3]	Dermal Dose (mg/kg/day)[4]	Dermal MOE[5]	Inhalation Dose (mg/kg/day)[6]	Inhalation MOE[7]	Total MOE[8]
Mixer/Loader										
Granules	Aerial applications	6.9 [Baseline, CR gloves]	1.7 [No respirator]	0.5 lb ai/acre	1200 acres	0.0037	2,700	0.0128	780	610
	Tractor-drawn spreader applications				200 acres	0.00062	16,000	0.00213	4,700	3,600
Liquids	Aerial applications	37.6 [Baseline, CR gloves]	0.219 [No respirator]		1200 acres	0.0203	490	0.00164	6,100	450
	Groundboom applications				200 acres	0.0034	3,000	0.00027	36,000	2,800
Applicator										
Granules	Aerial applications	1.7 [Engineering control (enclosed cockpit)]	1.3 [Engineering control (enclosed cockpit)]	0.5 lb ai/acre	1200 acres	0.00092	11,000	0.00975	1,000	920
	Tractor-drawn spreader applications	7.2 [Baseline, CR gloves]	1.2 [No respirator]		200 acres	0.00065	15,000	0.0015	6,700	4,600
Liquids	Aerial applications	5 [Engineering control (enclosed cockpit)]	0.068 [Engineering control (enclosed cockpit)]		1200 acres	0.0027	3,700	0.00051	20,000	3,100
	Groundboom applications	16.1 [Baseline, CR gloves]	0.34 [No respirator]		200 acres	0.0015	6,900	0.000085	190,000	5,400
Flagger										
Granules	Aerial applications	2.73 [Baseline, CR gloves]	0.15 [No respirator]	0.5 lb ai/acre	350 acres	0.00189	23,000	0.00033	30,000	13,000
Liquids	Aerial applications	12 [Baseline, CR gloves]	0.35 [No respirator]		350 acres	0.00043	5,300	0.00077	13,000	3,800
Mixer/loader/Applicator										
Liquids	Backpack sprayer	8260 [Baseline, CR gloves]	2.58 [No respirator]	0.1 lb ai/gallon	40 gallons	0.0297	340	0.000129	78,000	340
Granules	Belly grinder	9300 [Baseline, CR gloves]	62 [No respirator]	0.5 lb ai/acre	1 acre	0.00419	2,400	0.000388	26,000	2,200
	Rotary spreader	240 [Baseline, CR gloves]	10 [No respirator]		5 acres	0.00054	19,000	0.000313	32,000	12,000

[1] Unit exposures from PHED/ORETF/AHETF/etc. See: http://www.epa.gov/pesticides/science/handler-exposure-data.html. Baseline = single-layer (SL) of clothing (long-sleeve shirt, long pants, shoes/socks). CR = chemical-resistant.
[2] Based on proposed labels.
[3] Exposure Science Advisory Council Policy #9.1.
[4] Dermal Dose = Dermal Unit Exposure (ug/lb ai) x Conversion Factor (0.001 mg/ug) x Application Rate (lb ai/acre or gal) x Area Treated or Amount Handled (A or gal/day) x DAF (%) / BW (kg).
[5] Dermal MOE = Dermal NOAEL (mg/kg/day)/Dermal Dose (mg/kg/day).
[6] Inhalation Dose = Inhalation Unit Exposure (ug/lb ai) x Conversion Factor (0.001 mg/ug) x Application Rate (lb ai/acre or gal) x Area Treated or Amount Handled (A or gal/day) / BW (kg).
[7] Inhalation MOE = Inhalation NOAEL (mg/kg/day)/ Inhalation Dose (mg/kg/day).
[8] Total MOE = 1/(1/Dermal MOE + 1/Inhalation MOE).

Table 9.1.2. Short-Term Occupational Exposure and Risk Estimates for Imidacloprid Applications to Sugarcane in LA.

Crop or Target	Unit Exposure[1] (µg ai/lb handled)	Application Rate[2] (lb ai/A)	Units Treated[3] (A/day)	Avg. Daily Dose[4] (mg ai/kg bw/day)	Short-term MOEs[5]	Total MOE[6]
Mixer/Loader – Liquid – Aerial Applications						
Sugarcane	Dermal Baseline[7]: 220 Inhalation Baseline: 0.219	0.08	1200	Dermal Baseline: 0.019 Inhalation Baseline: 0.00026	Dermal Baseline: 530 Inhalation Baseline: 38,000	520
Applicator – Aerial Applications						
Sugarcane	Dermal Eng. Control[8]: 5.0 Inhalation Eng. Control: 0.065	0.08	1200	Dermal Baseline: 0.00432 Inhalation Baseline: 0.000082	Dermal Baseline: 23,000 Inhalation Baseline: 120,000	19,000
Flagger						
Sugarcane	Dermal Baseline: 11 Inhalation Baseline: 0.35	0.08	350	Dermal Baseline: 0.00028 Inhalation Baseline: 0.00012	Dermal Baseline: 36,000 Inhalation Baseline: 82,000	25,000

[1] Unit Exposures are taken from "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table," March, 2012.
[2] Application Rate. = Taken from proposed use information.
[3] Units Treated are taken from "Standard Values for Daily Acres Treated in Agriculture"; ExpoSAC SOP No. 9.1, revised 25 September 2001.
[4] Average Daily Dose = Unit Exposure * Applic. Rate * Units Treated * Absorption factor (dermal only = 7.2%) ÷ 80 kg Body Weight.
[5] MOE = Margin of Exposure = NOAEL ÷ ADD. NOAEL = 10 mg/kg bw/day (dermal), 10 mg/kg bw/day (inhalation).
[6] Total MOE = NOAEL ÷ (Combined Dermal + Inhalation Dose).
[7] Baseline = Long-sleeve shirt, long pants, and no gloves (dermal); no respirator (inhalation).
[8] Engineering Control = enclosed cockpit and baseline attire (long-sleeve shirt, long pants, shoes, and socks).

9.2 Post-Application Exposure and Risk Estimates

HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

For the proposed Section 3 use of imidacloprid on oyster beds, the extent of post-application exposure is expected to be non-occupational in nature. Thus, any occupational post-application dermal or inhalation exposures (e.g., during oyster harvesting) are adequately covered by the residential post-application assessment in Section 6.2. Based on the proposed Section 18 Emergency Exemption use of imidacloprid on sugarcane, occupational post-application dermal exposures are expected.

9.2.1 Dermal Post-application Exposure and Risk Estimates

HED expects that post-application exposure will occur since imidacloprid is applied as a foliar spray. Post-application exposure is expected to be short-term based on information provided on

the label (a maximum of 2 applications per crop cycle). However, the short- and intermediate-term toxicological endpoints are the same; therefore, the estimates of risk for short-term duration exposures are protective of those for intermediate-term duration exposures.

It is the policy of HED to use the best available data to assess post-application exposure. Sources of generic post-application data, used as surrogate data in the absence of chemical-specific data, are derived from ARTF exposure monitoring studies, and, as proprietary data, are subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting post-application exposure that are used in this assessment, known as "transfer coefficients," are presented in the "Science Advisory Council for Exposure (ExpoSAC) Policy 3" (http://www.epa.gov/pesticides/science/exposac_policy3.pdf), which, along with additional information about the ARTF data, can be found at http://www.epa.gov/pesticides/science/post-app-exposure-data.html.

A summary of the post-application MOEs and respective reentry intervals is provided in Table 9.2.1. The short-term post-application assessments for sugarcane resulted in MOEs of 100 or greater on "day 0" (immediately after application) for all exposure activities, and are not of concern.

Table 9.2.1. Summary of Short-term Occupational Post-application Risk Estimates.

Crop/Site	Transfer Coefficient (cm^2/hr)	Application Rate (lb ai/A)	DFR on Day 0 (ug/cm2)	Day 0 ST MOE[2]	Day X at which ST MOE ≥ LOC
Sugarcane	70 (hand weeding)	0.08	0.224	88,000	0
	1100 (scouting)			5,600	0
	17,600 (hand harvesting)			350	0

[1] DFR = AR x F x (1-D)[1] x 4.54E8 µg/lb x 2.47E-8 acre/cm^2.
[2] MOE = POD (NOAEL, 10 mg/kg/day) / Daily Dermal Dose. Daily Dermal Dose = [DFR (µg/cm^2) x TC x 0.001 mg/µg x 8 hrs/day x 7.2% dermal absorption] ÷ body weight 80 kg adult).

9.2.2 Inhalation Post-application Exposure and Risk Estimates

Based on the Agency's current practices, a quantitative inhalation post-application inhalation exposure assessment was not performed at this time primarily because of the low acute inhalation toxicity (Toxicity Category IV) and low vapor pressure (4×10^{-7} mmHg). However, there are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated areas. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its FIFRA SAP in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency is in the process of evaluating the SAP report as well as available post-application inhalation exposure data generated by the ARTF and may, as appropriate, develop policies and procedures, to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for imidacloprid.

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Appendix A. Toxicology Profile and Executive Summaries.

Table A.1. Acute Toxicity of Imidacloprid.

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
81-1	Acute Oral	42055331	LD_{50} = 424 mg/kg (M) LD_{50} >450 mg/kg (F)	II
81-2	Acute Dermal	42055332	LD_{50} >5000 mg/kg	IV
81-3	Acute Inhalation	42256317	LC_{50} >5.33 m/L	IV
81-4	Primary Eye Irritation	42055334	Not ao eye irritant	IV
81-5	Primary Skin Irritation	42055335	Not a dermal irritant	IV
81-6	Dermal Sensitization	42055336	Not a dermal sensitizer	N/A

Table A.2. Toxicity Profile of Imidacloprid Technical.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-Day oral toxicity rodents (rats)	NA	NA
870.3150 90-Day oral toxicity (nonrodents)	NA	NA
870.3200 21/28-Day dermal toxicity (rabbits)	42256329 (1990) Acceptable/guideline 0 or 1000 mg/kg/day 6 hr/day, 5 d/week	NOAEL = 1000 mg/kg/day (HDT). LOAEL = not identified.
870.3250 90-Day dermal toxicity	NA	NA
870.3465 4-Week inhalation toxicity (rat)	42273001 (1989) Acceptable/guideline 0, 0.0055, 0.035, or 0.191 mg/L/day, 6 hr/day, 5 d/week for 4 weeks	NOAEL = 0.191 mg/L/day (HDT). LOAEL = not identified.
870.3700a Preoatal developmental toxicity (rats)	42256338 (1992) Acceptable/guideline F: 0, 10, 30, or 100 mg/kg/day	**Maternal** NOAEL = 10 mg/kg/day. LOAEL = 30 mg/kg/day based on decreased body-weight gain and decreased corrected body-weight gain. **Developmental** NOAEL = 30 mg/kg/day. LOAEL = 100 mg/kg/day based on a slight increase in the incidence of wavy ribs.
870.3700b Prenatal developmental toxicity (rabbits)	42256339 (1992) Acceptable/guideline F: 0, 8, 24, or 72 mg/kg/day	**Maternal** NOAEL = 24 mg/kg/day. LOAEL = 72 mg/kg/day based on matemal deaths and decreased matemal absolute body weights, body-weight gains, and food consumption. **Developmental** NOAEL = 24 mg/kg/day. LOAEL = 72 mg/kg/day based on abortion, total litter resorptions, increased post-implantation loss due to increased late resorptions, decreased fetal weights, and very low incidences of skeletal alterations.
870.3800 Reproduction and fertility effects (rats)	42256340 (1990) Acceptable/guideline 0, 100, 250, or 700 ppm F_0 (M/F): 0, 8.1/8.8, 20.1/22.1, or 56.7/62.8 mg/kg/day F_1 (M/F): 0, 6.4/7.2, 16.5/18.9, or 47.3/52.3 mg/kg/day	**Parental/Systemic** NOAEL = 16.5 mg/kg/day. LOAEL = 47.3 mg/kg/day based on decreased premating weight gain by F_0 males and females and F_1 females and decreased gestational weight gain by F_1 females. **Reproductive** NOAEL = 47.3 mg/kg/day (HDT). LOAEL = not identified. **Offspring** NOAEL = 16.5 mg/kg/day. LOAEL = 47.3 mg/kg/day based on decreased pup body weights io both litters of both generations.
870.4100a Chronic toxicity (rodents)	NA; see 870.4300	NA
870.4100b Chronic toxicity (dogs)	42273002 (1989) Acceptable/guideline 0, 200, 500, or 1250/2500 ppm M/F: 0, 6.1, 15, or 41(first 16 wks.), then 72 mg/kg/d	NOAEL = 72 mg/kg/day (HDT). LOAEL = not identified.
870.4200a Carcinogenicity (rats)	NA; see 870.4300	NA
870.4200b	42256335 (1991)	NOAEL = Males: 208 mg/kg/day; Females: 274 mg/kg/day.

Table A.2. Toxicity Profile of Imidacloprid Technical.		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
Carcinogenicity (mice)	Acceptable/guideline with 42256336 0, 100, 330, or 1000 ppm M: 0, 20, 66, or 208 mg/kg/day F: 0, 30, 104, or 274 mg/kg/day 42256336 (1991) 0 or 2000 ppm M: 0 or 414; F: 0 or 424 mg/kg/day	LOAEL = Males: 414 mg/kg/day; Females: 424 mg/kg/day based on decreased body weights, food consumption and water intake. No evidence of carcinogenicity.
870.4300 Combined Chronic/carcinogenicity (rats)	42256331 (1989) Acceptable/guideline with 42256332 0, 100, 300, or 900 ppm M: 0, 5.7, 16.9, or 51.3 mg/kg/day F: 0, 7.6, 24.9, or 73.0 mg/kg/day 42256332 (1991) 0 or 1800 ppm M: 0 or 102.6; F: 0 or 143.7 mg/kg/day	NOAEL = Males: 5.7 mg/kg/day; Females: 7.6 mg/kg/day. LOAEL = Males: 16.9 mg/kg/day; Females: 24.9 mg/kg/day based on thyroid toxicity (increased incidence of mineralized particles in thyroid colloid) in males. No evidence of carcinogenicity.
870.5100 Bacterial reverse mutation	42256341 Acceptable/guideline	Negative for inducing reverse mutation in bacteria exposed to doses up to 5000 ug/plate.
870.5100 Bacterial reverse mutation	42256343 Acceptable/guideline	Negative up to 12,500 ug/plate.
870.5100 Bacterial reverse mutation	42256363 Acceptable/guideline	Negative up to 5500 ug/plate.
870.5300 *In vitro* mammalian cell gene mutation	42256342 Acceptable/guideline	Negative for inducing forward mutation in Chinese Hamster Ovary (CHO) (mammalian) cells treated up to 1222 ug/mL.
870.5300 *In vitro* mammalian cell gene mutation	42256364 Acceptable/guideline	Negative up to 2000 ug/mL.
870.5300 *In vitro* mammalian cell gene mutation	42256365 Acceptable/guideline	Negative up to 2000 ug/mL.
870.5375 *In vitro* mammalian chromosome abberation (HL)	42256345 Acceptable/guideline	Positive at 500 ug/mL - S9 and 1300 ug/mL +S9, both cytotoxic doses.
870.5375 *In vitro* mammalian chromosome abberation (CHV79)	42256370 Acceptable/guideline	Negative up to 1000 ug/mL.
870.5375 *In vitro* mammalian chromosome abberation (CHO)	42256371 Acceptable/guideline	Negative up to 1000 ug/mL.
870.5380 Mammalian germ cell chromosome abberation (mouse)	42256348 Unacceptable/guideline	Negative, but only tested up to 80 mg/ml.
870.5385 Mammalian bone marrow chromosome aberration (chinese hamster)	42256344 Acceptable/guideline	Negative for chromosome breakage up to 2000 ug/mL.
870.5395 Mammalian micronucleus (mouse)	42256347 Unacceptable/guideline	Negative, but only tested up to 80 mg/kg.
870.5395 Mammalian micronucleus (mouse)	42256366 Acceptable/guideline	Negative up to 50 mg/kg IP, toxic dose.
870.5395 Mammalian micronucleus (mouse)	42256367 Unacceptable/guideline	Negative up to 80 mg/kg IP, a non-toxic dose.
870.5395 Mammalian micronucleus (mouse)	42256368 Unacceptable/guideline	Negative up to 100 mg/kg PO, a non-toxic dose.
870.5395 Mammalian micronucleus (mouse)	42256369 Acceptable/guideline	Negative up to 160 mg/kg PO, toxic dose.

Table A.2. Toxicity Profile of Imidacloprid Technical.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.5500 DNA damage/repair *REC* assay	41156351 Acceptable/guideline	Negative up to 5000 ug/disc, the limit of solubility, with or without activation.
870.5550 Unscheduled DNA synthesis (RPH)	42256352 Acceptable/guideline	Negative up to 750 ug/mL, a cytotoxic dose.
870.5575 Mitotic gene conversion	42256353 Acceptable/guideline	Negative for crossing-over in yeast cells exposed with/without activation to precipitating levels of test article (5,000-10,000 ug/mL).
870.5550 Unscheduled DNA synthesis (RPH)	42256372 Acceptable/guideline	Negative up to cytotoxic doses (1333 ug/mL).
870.5900 *In vitro* sister chromatid exchange (CHO)	42256349 Acceptable/guideline	Positive at 500 ug/mL -S9 and 2000 ug/mL +S9, both cytotoxic doses.
870.5900 *In vitro* sister chromatid exchange (CHO)	47256350 Acceptable/guideline	Negative at cytotoxic doses of 400 ug/mL -S9 and 1250 ug/mL +S9.
870.59.15 *In vivo* sister chromatid exchange (chinese hamster bone marrow)	42256346 Acceptable/guideline	Negative up to 2000 mg/kg.
870.6200a Acute neurotoxicity screening battery rat	43170301 (1994) 43285801 (1994) Acceptable/guideline 0, 42, 151, or 307 mg/kg	NOAEL = not identified. LOAEL = 42 mg/kg based on decreased motor and locomotor activities observed in females.
870.6200b Subchronic neurotoxicity screening battery rat	43286401 (1994) Minimum 0, 150, 1000, or 3000 ppm M: 0, 9.3, 63.3, or 196 mg/kg/day F: 0, 10.5, 69.3, or 213 mg/kg/day	NOAEL = 9.3 mg/kg/day. LOAEL = 63.3 mg/kg/day based on decreased body-weight gain.
870.6300 Developmental neurotoxicity (rat)	45537501 (2001) Acceptable/non-guideline 0, 100, 250, or 750 ppm Gest.: 0, 8.0-8.3, 19.4-19.7, or 54.7-58.4 mg/kg/day Lact.: 0, 12.8-19.5, 30.0-45.4, or 80.4-155.0 mg/kg/day	**Maternal** NOAEL = 20 mg/kg/day. LOAEL = 55 mg/kg/day based on decreased food consumption and body-weight gain during lactation. **Offspring** NOAEL = 20 mg/kg/day. LOAEL = 55 mg/kg/day based on decreased body weight and body-weight gain, decreased motor activity and decreased caudate/putamen width in females.
870.7485 Metabolism and pharmacokinetics rat	42256354 (1990) 42256356 (1987) M&F: 1.0 or 20.0 mg/kg (labeled) as single oral dose or 1.0 mg/kg unlabeled orally followed by 1.0 mg/kg single oral dose (labeled) or 1.0 mg/kg (labeled) single dose IV. M: 20.0 mg/kg single oral dose or 1.0 mg/kg single duodenal dose. 42256357 (1991) M&F: 1.0 mg/kg single oral dose. M: 1.0 or 150 mg/kg single oral dose 42256373 (1990). M: 1.0 or 150 mg/kg single oral dose or 80.0 mg/kg single oral dose after 1 year 1800 ppm. 42256355 (1987) M: 1.0 mg/kg single oral	Methylene-labeled imidacloprid was rapidly absorbed with approximately 90% of the administered dose being eliminated within 24 hours and 96% within 48 hours. There were no biologically significant differences between sexes, dose levels, or route of administration. Urinary excretion was the major route of elimination (70-80% of recovered radioactivity), with a lesser amount eliminated in feces (17-25% of recovered radioactivity). Biliary excretion was a major contributor to fecal radioactivity (36.6% vs. 4.8% of recovered radioactivity in bile-fistulated animals). Total tissue burden after 48 hours accounted for only approximately 0.5% of the recovered radioactivity, with major sites of accumulation being the liver, kidney, lung, skin, and plasma and minor sites being the brain and testes. Maximum plasma concentration occurred between 1.1 and 2.5 hours, and elimination half-lives (calculated from two exponential terms) were 3 and 26-118 hours. There were two major evident routes of biotransformation. The first included an oxidative cleavage of the parent compound to give 6-CNA and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second included the hydroxylation of imidazolidine followed by elimination of water of the parent compound to give NTN 35884. In a comparison between [methylene-^{14}C]imidacloprid and [imidazolidine-4,5-^{14}C]imidacloprid, the rates of excretion were similar; however, the renal portion was higher with the imidazolidine-labeled test material. The imidazolidine-labeled test material also demonstrated higher accumulation in the tissues, with the major sites of accumulation being the liver, kidney,

Table A.2. Toxicity Profile of Imidacloprid Technical.		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
	or IV dose. 42256358 (1990) 42256359 (1990) Acceptable/guideline	lung, and skin, and the minor sites being brain and muscle. In a comparison between]methylene-^{14}C]imidacloprid and WAK 3839, there were no significant differences in the absorption, distribution, and excretion of the total radioactivity. More radioactivity was found in the tissues of the animals receiving imidacloprid at the 1.0 and 150.0 dose levels. The major sites of accumulation of WAK 3839 included lung, renal fat, liver, and kidney, with minor sites being the testis and brain. WAK 3839 was formed during pretreatment (chronic oral dosing) of imidacloprid; however, the proposed metabolic pathways of the two compounds were different.
870.7600 Dermal penetration	NA	NA

Appendix B. Physical/Chemical Properties.

Table B1. Physicochemical Properties of Imidacloprid.		
Parameter	**Value**	**Reference**
Molecular Weight	255.7	PP#6E7116; W. Cutchin, 14-May-2007; DP#s: 332757, 333517, & 334153 The Pesticide Manual Twelfth Edition (2000)
pH	5 to 11	
Water solubility (g/L at 23°C)	1.54	
Solvent solubility (g/L at 20°C)	Dichloromethane: 55, Isopropanol: 1.2, Toluene: 0.68, n-hexane: <0.1	
Vapor pressure (mPa at 20°C)	4×10^{-7}	
Octanol/water partition coefficient, log K_{ow} (25°C)	0.57 (21°C)	
Henry's law constant (@20°C)	6.5×10^{-11} atm m3/mole	Cal-EPA
Soil Half-life (or other relevant information from EFED Drinking water assessment)		R.Parker, 13-April-2007; DP#s: 334029, 334030, 332756, 333122, 333123, 333125, 333126, 330568, 330569
Hydrolysis half-life @ pH 7	Stable	
Photolysis half-life, distilled water (days)	0.2	
Photolysis half-life, soil (days)	39	
Aerobic soil half-life (days)	359	
Aerobic aquatic metabolism half-life (days)	27	
Soil leaching (K_{OC}, mL/g)	178 (132-256)	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 7-MAR-2013

SUBJECT: **Imidacloprid:** Section 3 Requests for Use on Oyster Beds.

PC Code: 129099
Decision No.: 461091
Petition No.: 2E7988
Risk Assessment Type: NA
TXR No.: NA
MRID No.: 48741901

DP Barcode: D400189
Registration No.: 264-758
Regulatory Action: Section 3 Registration
Case No.: 7605
CAS No.: 138261-41-3
40 CFR: §180.472

FROM: Jennifer R. Tyler, Chemist
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED; 7509P)

THROUGH: George F. Kramer, Ph.D., Branch Senior Chemist
RAB1/HED (7509P)

TO: Sidney Jackson/Barbara Madden, RM Team 05
Registration Division (RD; 7505P)

Executive Summary

The Interregional Research Project No. 4 (IR-4) has submitted a petition (PP# 2E7988) for the use of imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) on oyster beds to control burrowing shrimp. IR-4 has requested to add this use to the following labels: Protector 0.5G [a granular (G) product containing 0.5% imidacloprid as the active ingredient (ai); EPA Reg. No. xxx-xxx], and Protector 2F [a flowable concentrate (F) formulation containing 21.4% imidacloprid as the ai; EPA Reg. No. xxx-xxx). In conjunction with this petition, tolerances have been requested for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on fish at 0.05 ppm, and fish-shellfish, mollusc at 0.05 ppm.

The nature of imidacloprid residues in plants and livestock is adequately understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472.

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant [Bayer gas chromatography/mass spectrometry (GC/MS) Method 00200] and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method [high-performance liquid chromatography/ultraviolet (HPLC/UV) Method 00357] (Memos, F. Griffith, 6/18/93, D187911; 6/1/94, D202113; 6/8/94, D200233; 6/8/95, D213252; and 12/18/95, D221591). In the magnitude of the residue in oyster study, oyster meat samples were analyzed for residues of imidacloprid using a GC/MS method that is derived from the tolerance-enforcement method. The method was verified on oyster meat prior to and concurrent with sample analysis and is considered adequate based on acceptable recovery data. The fortification levels used in method validation and concurrent method recovery are adequate to bracket residues found in the submitted crop field trials.

Bayer Corporation previously submitted adequate multiresidue (MRM) recovery data for imidacloprid and the metabolites 5-hydroxy imidacloprid, imidacloprid olefin, des nitro imidacloprid, and 6-chloronicotinic acid (6-CNA) through Food and Drug Administration (FDA) Protocols A through E (Memos, F. Griffith, 6/18/93, D187911; 7/15/93, D193027; 6/8/94, D200233; and 6/22/94, D194206). Imidacloprid and its metabolites were not recoverable by these methods. The results of the MRM testing for imidacloprid were forwarded to FDA for inclusion in the Pesticide Analytical Method Volume I (PAM I) (Memo, F. Griffith, 7/15/93, D193005).

The available storage stability data are adequate to support the submitted magnitude of residue in oyster meat study. The maximum storage interval from collection to extraction was 112 days (3.7 months) from collection to analysis; including 8 days between extraction and analysis. Adequate storage stability data are available indicating that residues of imidacloprid and 6-CNA are stable in oyster meat at -15°C for at least 112 days and 119 days, respectively. Residues of imidacloprid have been shown to be stable in a variety of raw agricultural commodities (RACs) for up to 2 years (~728 days) of storage (Memo, F. Griffith, 6/8/95, PP#5F4480). Analysis of samples from the ^{14}C-imidacloprid plant metabolism studies for corn, cotton, apples, and potatoes showed no loss of imidacloprid and its major metabolites during a period of 2 years of frozen storage (Memo, F. Griffith, 9/21/93, D185148).

No magnitude of the residue in fish or nature of the residue in fish studies were submitted in support of the proposed use. However, the registrant recently submitted a waiver request for both studies. The request was presented to the HED Science Advisory Council for Chemistry (ChemSAC) on 23-FEB-2011, and the ChemSAC agreed with the rationale for the waiver (ChemSAC Minutes). Therefore, data demonstrating the magnitude of the residue or nature of the residue in fish are not necessary to support of the proposed use on oyster beds. The ChemSAC determined that the proposed tolerance for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on fish at 0.05 ppm is appropriate.

The submitted magnitude of the residue study in oysters was conducted in accordance with OPPTS Guideline 860.1400, and the data are adequate to support the proposed use. Total residues of imidacloprid were less than limit of quantitation [LOQ, defined as the lowest level of method validation, LLMV (0.05 ppm)] in/on oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G at an application rate of 0.50 lb ai/A; or Mallot 2F® at an application rate of 2.0 lb ai/A. Samples were analyzed for total imidacloprid residues using an acceptable method, and the study is supported by adequate storage stability data. For oysters, the Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedures could not be used to calculate a possible tolerance as residues of imidacloprid were <LOQ in/on all samples of oyster meat. Therefore, the tolerance of 0.05 ppm for fish-shellfish, mollusc is appropriate (see Section 860.1550 Proposed Tolerances).

Regulatory Recommendations and Residue Chemistry Deficiencies

HED concludes that the residue chemistry database is sufficient for unconditional registration and establishment of permanent tolerances for imidacloprid in or on the commodities listed below.

a) *General.* Tolerances are established for residues of the insecticide imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid, in or on the following commodities:

Fish	0.05 ppm
Fish-shellfish, mollusc	0.05 ppm

A human-health risk assessment for imidacloprid is forthcoming.

Background

Imidacloprid is an insecticide registered for uses on a variety of crops for the control of aphids, cucumber beetles, and whiteflies (including sweet potato or silverleaf whitefly). Imidacloprid is a member of the pyridylmethylamine class of compounds. Its mode of action is the disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid blocks the signals that are induced by acetylcholine at the post-synaptic membrane, resulting in normal nerve function impairment.

Tolerances are currently established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, under 40 CFR §180.472 in/on various plant and livestock commodities. Indirect or inadvertent tolerances are established as a result of application of the pesticide to growing crops and other non-food crops under 40 CFR §180.472(d). The nomenclature and physicochemical properties of imidacloprid are presented below in Tables 1 and 2.

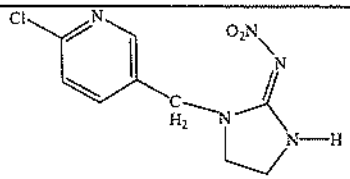
Table 1. Test Compound Nomenclature.	
Chemical Structure	
Common Name	Imidacloprid
Company experimental name	Imidacloprid
IUPAC name	(*EZ*)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine
CAS name	1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine
CAS #	138261-41-3
End-use products/(EP)	Protector 2F (EPA Reg. No. xxx-xxx) Protector 0.5G (EPA Reg. No. xxx-xxx)

Table 2. Physicochemical Properties of the Technical Grade Test Compound.		
Parameter	Value	**Reference**
Melting point	144°C	The Pesticide Manual Twelfth Edition (2000)
pH	5 to 11	
Specific gravity	1.54 (@ 23°C)	
Water solubility (g/L at 20°C)	0.61	
Solvent solubility (g/L at 20°C)	Dichloromethane: 55, Isopropanol: 1.2, Toluene: 0.68, n-hexane: < 0.1	
Vapor pressure (mPa at 20°C)	4×10^{-7}	
Octanol/water partition coefficient [Log(K_{OW})]	0.57 (21°C)	
UV/visible absorption spectrum	Not provided.	

860.1200 Directions for Use

The petitioner has submitted draft labels for the Protector 0.5G (EPA Reg. No. xxx-xxx), and Protector 2G (EPA Reg. No. xxx-xxx). A summary of the proposed use patterns is detailed in Table 3.

Table 3. Summary of Proposed Directions for Use of Imidacloprid.

Use Site	Trade Name (EPA Reg. No.)	Application Equipment	App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A)	PHI[1] (days)	Max. # App.	Min. GPA[2]	RTI[3] (days)
Oyster beds	Protector 0.5G (xxxxx-xx)	Drop/rotary spreader Tractor-drawn spreader Belly grinder Helicopter	0.5	0.5	30	1	NA	NA (only 1 treatment per acre per year)
	Protector 0.5F (xxxxx-xx)	Groundboom Helicopter Backpack	0.5	0.5	30	1	ground: 5 air: 2	

Restrictions:

- Not for sale to any persons other than a member of the Willapa-Greys Harbor Oyster Growers Association.
- A single application/year is allowed.
- No adjuvants or surfactants allowed.
- Aerial applications must be made on beds exposed at low tide.
- Applications from a floating platform or boat may be made under water using a calibrated granular applicator.
- All application must be made between April 15 and December 15. Do not apply aerially during Federal Holidays.
- During aerial applications, all public access areas and public boat launches within ¼ mile radius of bed shall be posted.

1. PHI = pre-harvest interval.
2. GPA = gallons of water per acre.
3. RTI = retreatment interval.

HED Conclusions: The use directions provided by the petitioner are adequate to allow evaluation of the residue data relative to the proposed use of imidacloprid on oyster beds to control ghost shrimp.

860.1300 Nature of the Residue - Plants and Livestock

Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant, cottonseed, field corn, tobacco, ruminants, and poultry have been submitted and reviewed (Memos, F. Griffith, 9/20/93, DP# 185148; 6/8/94, DP# 200233; and 2/29/96, DP# 217632). The results of the aforementioned plant and livestock metabolism studies were presented to the HED Metabolism Assessment Review Committee (MARC) on 6/22/93 (Memo, F. Griffith, 6/25/93, TXR#: 0050886). The nature of imidacloprid residues in plants and livestock is adequately understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472.

860.1340 Residue Analytical Methods

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant (Bayer GC/MS Method 00200) and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA PMVs, and the registrant has fulfilled the remaining requirements for additional raw data, method validation, ILV, and an acceptable confirmatory method (HPLC/UV Method 00357) (Memos, F. Griffith, 6/18/93, D187911; 6/1/94, D202113; 6/8/94, D200233; 6/8/95, D213252; and 12/18/95, D221591). The

limit of detection (LOD) and LOQ for the GC/MS Method 00200 are 0.01 and 0.05 ppm, respectively, in plant commodities.

In the magnitude of the residue in oyster study, oyster meat samples were analyzed for residues of imidacloprid using a GC/MS method entitled "Working Analytical Method for the Determination of Total Residues of Imidacloprid in Oysters," which is a modification of Bayer Method 00191 M001-Reformatted. In the method, imidacloprid and all metabolites containing chloropyridine moiety are oxidized into 6-CNA, which is then converted into trimethylsilyl ester prior to quantitation using GC/MS. For imidacloprid, based on the recoveries of samples fortified at the lowest LLMV, the LOD and LOQ were calculated as 0.014 ppm and 0.042 pm, respectively. For 6-CNA, the LOD and LOQ were calculated as 0.0048 ppm and 0.014 respectively. The method was verified on oyster meat prior to and concurrent with sample analysis and is considered adequate based on acceptable recovery data. The fortification levels used in method validation and concurrent method recovery are adequate to bracket residues found in the submitted crop field trials.

860.1360 MRM

Bayer Corporation previously submitted adequate MRM recovery data for imidacloprid and the metabolites 5-hydroxy imidacloprid, imidacloprid olefin, des nitro imidacloprid and 6-CNA through FDA Protocols A through E (Memos, F. Griffith, 6/18/93, D187911; 7/15/93, D193027; 6/8/94, D200233; and 6/22/94, D194206). Imidacloprid and its metabolites were not recoverable by these methods. The results of the MRM testing for imidacloprid were forwarded to FDA for inclusion in the PAM I (Memo, F. Griffith, 7/15/93, D193005).

`860.1380 Storage Stability

In the magnitude of the residue in oyster study, oyster meat samples were stored for a maximum of 112 days (3.7 months) from collection to analysis; including 8 days between extraction and analysis. Samples were stored below freezing (<-15°C) at the field sites and at the analytical laboratory prior to extraction. Adequate storage stability data are available indicating that residues of imidacloprid and 6-CNA are stable in oyster meat at -15°C for at least 112 days and 119 days, respectively. These data support the storage conditions and durations of imidacloprid for the oyster meat field trial samples.

In addition, residues of imidacloprid have been shown to be stable in a variety of RACs for up to 2 years (~728 days) of storage (Memo, F. Griffith, 6/8/95, PP#5F4480). Analysis of samples from the ^{14}C-imidacloprid plant metabolism studies for corn, cotton, apples, and potatoes showed no loss of imidacloprid and its major metabolites during a period of 2 years of frozen storage (Memo, F. Griffith, 9/21/93, D185148).

860.1400 Water, Fish, and Irrigated Crops

Magnitude of the Residue in Fish and Nature of the Residue in Fish

No magnitude of the residue in fish or nature of the residue in fish studies were submitted in support of the proposed use. However, the registrant recently submitted a waiver request for both studies. The rationale in support of the waiver request was based on both the projected lack of significant uptake by fish, and the projected low dietary risk to sensitive populations in cases where residues of imidacloprid are found in fish (using the FISH model).

HED Conclusions: The waiver request was presented to the HED ChemSAC on 23-FEB-2011, and the ChemSAC concluded the following (ChemSAC Minutes):

> ChemSAC agreed that no fish metabolism or magnitude of the residue data are needed to support this use. However, it was suggested that risk assessment team contact EFED to see if their K_{OW}-based Aquatic Bioaccumulation Model (KABAM) model (a comparable model to FISH) has been used to project residues of imidacloprid in fish; and if so, were the results similar to the FISH model results. The ChemSAC also agreed that tolerances at the LOQ may need to be established for residues of imidacloprid in fish. The ChemSAC determined that there is a potential for Environmental Justice problems with this use. The risk assessment team should consult the most recent carbaryl RED for further guidance on this matter. It was noted that the carbaryl assessment should also be used as an example of a swimmer exposure assessment.

Therefore, data demonstrating the magnitude of the residue or nature of the residue in fish are not necessary to support of the proposed use on oyster beds. However, the proposed tolerance of 0.05 ppm (LOQ) for residues of imidacloprid in/on fish is appropriate (see Section 860.1550 Proposed Tolerances).

It should be noted the EFED was contacted to see if their KABAM model (a comparable model to FISH) has been used to project residues of imidacloprid in fish. EFED reported that the KABAM model has not been used for imidacloprid (personal communication between J. Tyler and M. Barrett, 20-AUG-2012). Due to imidalcoprid's low Kow (3.7 @21°C) and low toxicity to fish, accumulation values are expected to be negligible.

Magnitude of the Residue in Oysters

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Table 4. Summary of Residue Data from Oyster Field Trials with Imidacloprid.

Commodity	Total App. Rate (lb ai/A)[2]	PHI (days)	Residue Levels (ppm)[1]							
			n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.
Oyster Meat	0.525-0.590	28	2	ND	ND	-	-	-	-	-
		57	2	ND	ND	-	-	-	-	-
		84-86	6	ND	<0.05	-	-	-	-	-
	1.87-2.02	27	2	<0.05	<0.05	-	-	-	-	-
		56	2	<0.05	<0.05	-	-	-	-	-
		84-85	6	ND	<0.05	-	-	-	-	-

1. LLMV= 0.05 ppm.
2. One application of Mallol® 0.5B at approximately 0.50 lb ai/A, or one application of Mallet® 2F at approximately 2.0 lb ai/A.
3. LAFT = lowest average field trial. HAFT = highest average field trial.

IR-4 has submitted data from a study examining residues of imidacloprid in oysters. Three supervised irrigated crop trials were conducted in Washington [North American Free Trade Agreement (NAFTA)] Growing Zone 12 during the 2010 growing season.

Two treated plots were established in each trial, one for the granular formulation (Mallot® 0.5G, TRT 02), and one for the flowable concentrate formulation (Mallot® 2F, TRT 03). In TRT02, a single application of imidacloprid was made using either a drop spreader or hand spreader at an application rate of approximately 0.50 ai/A. In TRT03, a single application of imidacloprid was made using a backpack sprayer at an application rate of 2.0 lb ai/A. All applications were made at low tide. In WA44, TRT 02 was overapplied by approximately 18%, and TRT 03 was underapplied by approximately 6.5%. Oyster samples were collected from each plot 84-86 days following applications; and, additional oyster samples were collected from the treated plots in WA43 at approximately 30 and 60 days. Shucked meat was retained as samples.

Total residues of imidacloprid were below the LLMV (0.05 ppm) in oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G (TRT02) at an application rate of 0.50 lb ai/A; or Mallot® 2F (TRT03) at an application rate of 2.0 lb ai/A.

HED Conclusions: The magnitude of the residue study was conducted in accordance with OPPTS Guideline 860.1400, and the data are adequate to support the proposed use. Total residues of imidacloprid were <LLMV (0.05 ppm) in/on oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G (TRT02) at an application rate of 0.50 lb ai/A; or Mallot 2F® (TRT03) at an application rate of 2.0 lb ai/A. Samples were analyzed for total imidacloprid residues using an acceptable method, and the study is supported by adequate storage stability data.

For oysters, the OECD tolerance-calculation procedures could not be used to calculate a possible tolerance as residues of imidacloprid were <LOQ in/on all samples of oyster meat. Therefore, the recommended tolerance is 0.05 ppm for fish-shellfish, mollusc is appropriate (see Section 860.1550 Proposed Tolerances).

860.1480 Meat, Milk, Poultry, and Eggs

There are no livestock feed items associated with the proposed use; therefore, residue data on livestock commodities are not required to support the subject petition.

860.1500 Crop Field Trials

As there are no proposed uses on primary crops associated with the subject petition, crop field trial data are not required.

860.1520 Processed Food and Feed

As there are no processed commodities associated with the proposed use, a processing study is not required to support the subject petition.

860.1550 Proposed Tolerances

A summary of the proposed and recommended tolerances for the proposed uses are listed in Table 5.

Table 5. Tolerance Summary for Imidacloprid.

Commodity	Proposed Tolerance (ppm)	Currently Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (*correct commodity definition*)
fish	0.05	-	0.05	
fish-shellfish, mollusc	0.05	-	0.05	

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for imidacloprid on fish or molluscs. An International Residue Limit Status Sheet is attached in Appendix I.

860.1850 and 860.1900 Confined/Field Accumulation in Rotational Crops

According to the current guidance, rotational crop studies are not required for the subject petitions.

Attachment 1: IRLS Sheet.

cc: J. Tyler
RDI: RAB1 Chemists (9/xx/12); G. Kramer (9/7/12)
J. Tyler: S-10943: Potomac Yard 1 (PY1): (703) 305-5564: 7509P: RAB1

Attachment 1: IRLS Sheet.

Imidacloprid (129099; Date of Request: 08/30/2012)

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	Canada		Mexico[2]	Codex[3]
40 CFR §180.472: sum of imidacloprid (1-[6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid	1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, including metabolites containing the 6-chloropicolyl moiety			Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety
Commodity[1]	*Tolerance (ppm)/Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex[3]
fish	0.05			
fish, shellfish, mollusc	0.05			
Completed: M. Negussie; 08/31/2012				

[1] Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.

[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

[3] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

Primary Evaluator	Jennifer R. Tyler, Chemist Risk Assessment Branch 1 (RAB1) Health Effects Division (HED) (7509P)	Date: 7-MAR-2012
Approved by	George F. Kramer, Ph.D., Senior Chemist RAB1/HED (7509P)	Date: 7-MAR-2012

STUDY REPORTS:

48741901. Dorschner, K. (2011) Imidacloprid: Magnitude of Residue on Oyster. IR-4 PR No.: 10553. Unpublished study prepared by IR-4. 142 p.

EXECUTIVE SUMMARY:

Interregional Research Project No. 4 (IR-4) has submitted data from a study examining residues of imidacloprid in oysters. Three supervised irrigated crop trials were conducted in Washington [North American Free Trade Agreement (NAFTA) Growing Zone 12] during the 2010 growing season.

Two treated plots were established in each trial, one for the granular formulation (Mallot® 0.5G, TRT 02), and one for the flowable concentrate formulation (Mallot® 2F, TRT 03). In TRT02, a single application of imidacloprid was made using either a drop spreader or hand spreader at an application rate of approximately 0.50 pounds (lb) active ingredient (ai)/acre (A). In TRT03, a single application of imidacloprid was made using a backpack sprayer at an application rate of 2.0 lb ai/A. All applications were made at low tide. In WA44, TRT 02 was overapplied by approximately 18%, and TRT 03 was underapplied by approximately 6.5%. Oyster samples were collected from each plot 84-86 days following applications; and, additional oyster samples were collected from the treated plots in WA43 at approximately 30 and 60 days. Shucked meat was retained as samples.

Oyster meat samples were analyzed for residues of imidacloprid using a gas chromatography/ mass spectrometry (GC/MS) method entitled "Working Analytical Method for the Determination of Total Residues of Imidacloprid in Oysters," which is a modification of Bayer Method 00191 M001-Reformatted. In the method, imidacloprid and all metabolites containing chloropyridine moiety are oxidized into 6-chloronicotinic acid (6-CNA), which is then converted into trimethylsilyl ester prior to quantitation using GC/MS. For imidacloprid, based on the recoveries of samples fortified at the lowest limit of method validation (LLMV), the limit of detection (LOD) and limit of quantitation (LOQ) were calculated as 0.014 ppm and 0.042 pm, respectively. For 6-CNA, the LOD and LOQ were calculated as 0.0048 ppm and 0.014 respectively. The method was verified on oyster meat prior to and concurrent with sample analysis and is considered adequate based on acceptable recovery data. The fortification levels used in method validation and concurrent method recovery are adequate to bracket residues found in the submitted crop field trials.

Oyster meat samples were stored for a maximum of 112 days (3.7 months) from collection to analysis; including 8 days between extraction and analysis. Samples were stored below freezing (<-15°C) at the field sites and at the analytical laboratory prior to extraction. Adequate storage stability data are available indicating that residues of imidacloprid and 6-CNA are stable in oyster meat at -15°C for at least 112 days and 119 days, respectively. These data support the storage conditions and durations of imidacloprid for the oyster meat field trial samples.

Total residues of imidacloprid were below the LLMV (0.05 ppm) in oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G (TRT02) at an application rate of 0.50 lb ai/A; or Mallot® 2F (TRT03) at an application rate of 2.0 lb ai/A.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document (DP#: 400189).

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance, and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Imidacloprid is a systemic chloro-nicotinyl insecticide with registered foliar, soil, and seed treatment uses on several agricultural crops for the control of sucking insects including wireworms, seed corn maggots, flea beetles, aphids, thrips, and chinch bugs. The mode of action is similar to that of nicotine in that it mimics the action of the acetylcholine in the nerve synapse, causing tremors, loss of coordination, and eventual death. The chemical structure and nomenclature of imidacloprid and 6-CNA are presented in Table A.1. The physicochemical properties of the technical grade of imidacloprid are presented in Table A.2.

TABLE A.1. Test Compound Nomenclature.

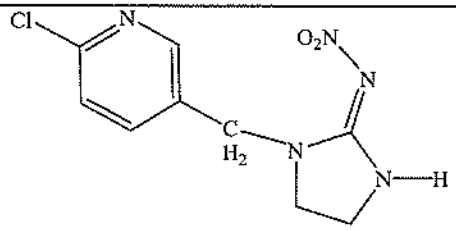
Chemical Structure	
Common Name	Imidacloprid
Company experimental name	Imidacloprid
IUPAC name	(*EZ*)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine

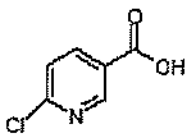
TABLE A.1. Test Compound Nomenclature.	
CAS name	1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine
CAS #	138261-41-3
End-use products/(EP)	Mallot® 0.5G Mallot® 2F
Metabolite	Chemical Structure 
Common name	6-chloronicotinic acid
CAS name	6-Chloro-3-pyridinecarboxylic acid
CAS #	5326-23-8

TABLE A.2. Physicochemical Properties of the Parent Compound Imidacloprid.		
Parameter	Value	Reference
Melting point	144°C	PP#6E7116; W. Cutchin, 14-May-2007; DP#s: 332757, 333517, & 334153
pH	5 to 11	
Specific gravity	1.54 (@ 23°C)	
Water solubility (g/L at 20°C)	0.61	
Solvent solubility (g/L at 20°C)	Dichloromethane: 55, Isopropanol: 1.2, Toluene: 0.68, n-hexane: < 0.1	
Vapor pressure (mPa at 20°C)	4×10^{-7}	
Octanol/water partition coefficient [Log(K_{OW})]	0.57 (21°C)	
UV/visible absorption spectrum	Not provided.	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Three field trials were conducted in the U.S. during the 2010 growing season in WA (NAFTA Growing Zone 12). Two treated plots were established in each trial, one for the granular formulation (Mallot® 0.5G, TRT 02), and one for the flowable-concentrate formulation (Mallot® 2F, TRT 03). In TRT02, a single application of imidacloprid was made using either a drop spreader or hand spreader at an application rate of approximately 0.50 lb ai/A. In TRT03, a single application of imidacloprid was made using a backpack sprayer at an application rate of 2.0 lb ai/A. All applications were made at low tide. In WA44, TRT 02 was overapplied by approximately 18%, and TRT 03 was underapplied by approximately 6.5%.

Oyster samples were collected from each plot 84-86 days following applications; and, additional oyster samples were collected from the treated plots in WA43 at approximately 30 and 60 days. Shucked meat was retained as samples.

For each field trial, the petitioner presented the temperature during each application, the time of exposure to tide after application, and the amount of exposure to high tide after application. The petitioner indicated that there were no abnormal weather events that adversely affected crop yields or crop growth and development.

Trial conditions are presented in Table B.1.1. The study use pattern is presented in Table B.1.2, and the trial numbers and geographical locations are identified in Table B.1.3.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Year)	Soil Characteristics			
	Type	%OM[1]	pH	CEC (meq/g)[2]
10-WA43 (Oysterville, WA/2010)	Sand	1.10	6.87	16.14
10-WA44 (Oysterville, WA/2010)	Sand	1.10	6.87	16.14
10-WA45 (Long Beach, WA/2010)	Sand	1.82	7.16	19.14

1. %OM = percent organic matter.
2. CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Patterns.

Location (City, State/Year) Trial ID	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing	Delivery Rate	Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)	
10-WA43 (Oysterville, WA/2010)	Mallot 0.5G	Broadcast to ground/3- to 5-year old oysters/ 28 days prior to harvest	105.52 lb/A	0.528	-	0.528	None
	Mallot 2F	Broadcast to ground/3- to 5-year old oysters/28 days prior to harvest	18.54 gal/A	1.93	-	1.93	None
10-WA44 (Oysterville, WA/2010)	Mallot 0.5G	Broadcast to ground/3- to 5-year old oysters/ 86 days prior to harvest	117.93 lb/A	0.590[3]	-	0.590	None
	Mallot 2F	Broadcast to ground/3- to 5-year old oysters/ 85 days prior to harvest	31.90 gal/A	1.87[4]	-	1.87	None
10-WA45 (Long Beach, WA/2010)	Mallot 0.5G	Broadcast to ground/3- to 5-year old oysters/ 84 days prior to harvest	105 lb/A	0.525	-	0.525	None
	Mallot 2F	Broadcast to ground/3- to 5-year old oysters/ 84 days prior to harvest	37.46 gal/A	2.02	-	2.02	None

1. EP = end-use product.
2. RTI = retreatment interval.
3. The test substance was overapplied by approximately 18%.
4. The test substance was underapplied by approximately 6.5%.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Oysters		
	Submitted	Requested*	
		Canada	U.S.
12	3	-	-
Total	3	-	-

B.2. Sample Handling and Preparation

In each trial, oysters were collected from each plot 84 and 86 days after treatment. In the WA43 trial, additional oysters were collected from each plot at days approximately 30 and 60 days

following application. The samples were collected in a manner to assure a representative sample. After the oysters were shucked with a knife, the shells were discarded, and the oyster meat retained as samples. The samples were placed in cooler containing dry ice within approximately 3 minutes of sampling. The samples were then transported to freezers until shipment on dry ice/blue ice to the Food and Environmental Quality Laboratory, Richland, WA, where the samples were stored frozen. The tissue samples were later homogenized in the presence of dry ice and returned to the freezer until extraction and analysis.

B.3. Analytical Methodology

Samples were analyzed for total residues of imidacloprid using Method FEQL Project No.: 0410, entitled "Working Analytical Method for the Determination of Total Residues of Imidacloprid in Oysters." This working method is a derivation of Bayer Method 00191 M001-Reformatted, "Method for the Determination of Total Residues of Imidacloprid in Animal Materials." In the method, imidacloprid and all metabolites containing chloropyridine moiety are oxidized into 6-CNA, which is then converted into trimethylsilyl ester prior to quantitation using GC/MS. For imidacloprid, based on the recoveries of samples fortified at the LLMV, the LOD and LOQ were calculated as 0.014 ppm and 0.042 pm, respectively. For 6-CNA, the LOD and LOQ were calculated as 0.0048 ppm and 0.014 respectively.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2.1. Oyster meat samples were stored for a maximum of 112 days (3.7 months) from collection to analysis; including 8 days between extraction and analysis. Samples were stored below freezing (<-15°C) at the field sites and at the analytical laboratory prior to extraction. Adequate storage stability data are available indicating that residues of imidacloprid and 6-CNA are stable in oyster meat at -15°C for at least 112 days and 119 days, respectively. These data support the storage conditions and durations of imidacloprid for the oyster meat field trial samples.

Method validation and concurrent method recovery data for the GC/MS method are presented in Table C.1. For method validation, samples of untreated oyster meat were fortified at 0.05 ppm or 0.5 ppm with imidacloprid, or 0.05 ppm with 6-CNA. For concurrent method validation, samples were fortified at 0.05 ppm with imidacloprid or 6-CNA. Recoveries for each sample analysis were within the acceptable range of 70-120%. The method is considered adequate based on the acceptable method validation and concurrent recovery data. The fortification levels used in method validation and concurrent method recovery are adequate to bracket residues found in the submitted crop field trials.

Residue data from the oyster field trials are reported in Table C.3. A summary of residue data for oyster meat is presented in Table C.4. Total residues of imidacloprid were <LLMV (0.05 ppm) in oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G (TRT02) at an application rate of 0.50 lb ai/A; or Mallot® 2F (TRT03) at an application rate of 2.0 lb ai/A.

TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Imidacloprid from Oyster Meat.

Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Method Validation					
Oyster Meat	Imidacloprid	0.05	3	82-105	90 ± 13
		0.5	3	72-82	88±10
Concurrent Recovery					
Oyster Meat	Imidacloprid	0.05	10	73-101	77±5
	6-CNA	0.05	6	97-105	100±3

TABLE C.2. Summary of Storage Conditions.

Matrix	Analyte	Storage Temperature (°C)	Actual Storage Duration[1] (days)	Interval of Demonstrated Storage Stability	Fortification Level (ppm)	Storage Stability Recoveries (%)
Oyster Meat	Imidacloprid	<-15	112	112	0.5	82
						73
						77
	6-CNA			119	0.5	87
						87
						88

1. Storage duration from collection to extraction; extracts were analyzed within 8 days of extraction.

TABLE C.3. Residue Data from Crop Field Trials with Imidacloprid.

Trial ID (City, State/Year)	NAFTA Growing Region	Crop/Variety	Commodity	TRT No.	Total Rate (lb ai/A)[1]	PHI (days)	Residues (ppm)[2]	Mean[3]
10-WA43 (Oysterville, WA/2010)	12	Oyster/Pacific Diploid	Oyster Meat	02	0.528	28	ND, ND	0.05*
						57	ND, ND	0.05*
						86	ND, ND	0.05*
				03	1.93	27	<0.05, <0.05	0.05*
						56	<0.05, <0.05	0.05*
						85	<0.05, <0.05	0.05*
10-WA44 (Oysterville, WA/2010)	12	Oyster/Pacific Diploid	Oyster Meat	02	0.590[4]	86	ND, ND	0.05*
				03	1.87[5]	85	ND, ND	0.05*
10-WA45 (Long Beach, WA/2010)	12	Oyster/Triploid	Oyster Meat	02	0.525	84	ND, ND	0.05*
				03	2.02	84	ND, ND	0.05*

1. One application of Mallet® 0.5G at approximately 0.50 lb ai/A (TRT 02) or one application of Mallet® 2F at approximately 2.0 lb ai/A (TRT 03).
2. Imidacloprid equivalents of trimethylsilyl 6-chloronicotinate (6-CNA). ND = non-detect.
3. Mean residue. For residues <0.05 ppm, a value of 0.05 ppm is used to calculate the mean. An asterisk indicates that all residues in samples from this trial were below the LLMV (0.05 ppm).
4. The test substance was overapplied by approximately 18%.
5. The test substance was overapplied by approximately 6.5%.

TABLE C.4. Summary of Residue Data from Oyster Field Trials with Imidacloprid.

Commodity	Total App. Rate (lb ai/A)[2]	PHI (days)	Residue Levels (ppm)[1]							
			n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.
Oyster Meat	0.525-0.590	28	2	ND	ND	-	-	-	-	-
		57	2	ND	ND	-	-	-	-	-
		84-86	6	ND	<0.05	-	-	-	-	-
	1.87-2.02	27	2	<0.05	<0.05	-	-	-	-	-
		56	2	<0.05	<0.05	-	-	-	-	-
		84-85	6	ND	<0.05	-	-	-	-	-

1. LLMV= 0.05 ppm.
2. One application of Mallot® 0.5B at approximately 0.50 lb ai/A, or one application of Mallet® 2F at approximately 2.0 lb ai/A.
3. LAFT = lowest average field trial. HAFT = highest average field trial.

D. CONCLUSION

The supervised residue trials on oysters are considered scientifically acceptable. Total residues of imidacloprid were <LLMV (0.05 ppm) in/on oyster meat harvested 26-86 days following either a single application of Mallot® 0.5G (TRT02) at an application rate of 0.50 lb ai/A; or Mallot 2F® (TRT03) at an application rate of 2.0 lb ai/A. Samples were analyzed for total imidacloprid residues using an acceptable method, and the study is supported by adequate storage stability data.

E. REFERENCES

None.

F. DOCUMENT TRACKING

RDI: G.F. Kramer (26-JUL-20012), RAB1 Chemists (26-JUL-2012)
Petition Number: 2E7988
DP#: 400189
PC Code: 129099

Template Version June 2005

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: March 13, 2013

SUBJECT: IR4 Petition for the Use of Imidacloprid on Shellfish Beds in Willapa Bay and Grays Harbor, State of Washington
(PC Code 129099; DP Barcode D399685, 399877, 399882)
DECISION: 461091, 461090, 461088 3/13/2013

FROM: Joseph DeCant, Ecologist
Michael Barrett, Senior Chemist 3/13/2013
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

THRU: Mah T. Shamim, Ph.D, Branch Chief 3/13/13
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

TO: Sidney Jackson, Risk Manager Reviewer
Barbara Madden, Minor Use Team Leader #05
Risk Integration, Minor Use and Emergency Response Branch
Registration Division (7505P)

The Environmental Fate and Effects Division (EFED) has completed its review of an IR4 new use petition for the use of imidacloprid (formulated as Protector 0.5G and Protector 2F) on shellfish beds at Willapa Bay and Grays Harbor in the state of Washington. Based upon a review of this new use and the labeled the maximum yearly use rate, the risks are outlined in **Table 1.**

Table 1. Summary of Environmental Risk Conclusions for Various Taxa Exposed to Imidacloprid for the Proposed Use on Shellfish Beds in Washington.

Assessment Endpoint	Identified Concerns
Acute and Chronic Risk to Estuarine/marine Fish	**None**
Acute and Chronic Risk to Estuarine/Marine Invertebrates	**Acute and Chronic on-site risk to free-swimming and benthic invertebrates; off-site acute risk to listed benthic invertebrates and chronic risk to benthic invertebrates due to flowable formulation**
Aquatic Non-Vascular and Vascular Plants	**None**
Birds	**Acute risk due to flowable formulation applied to exposed mudflats**

2088663

Mammals	None
Concerns to Terrestrial Non-Target Insects	**Concerns for invertebrates other than bees due to flowable formulation applied to exposed mudflats**
Terrestrial Plants	None

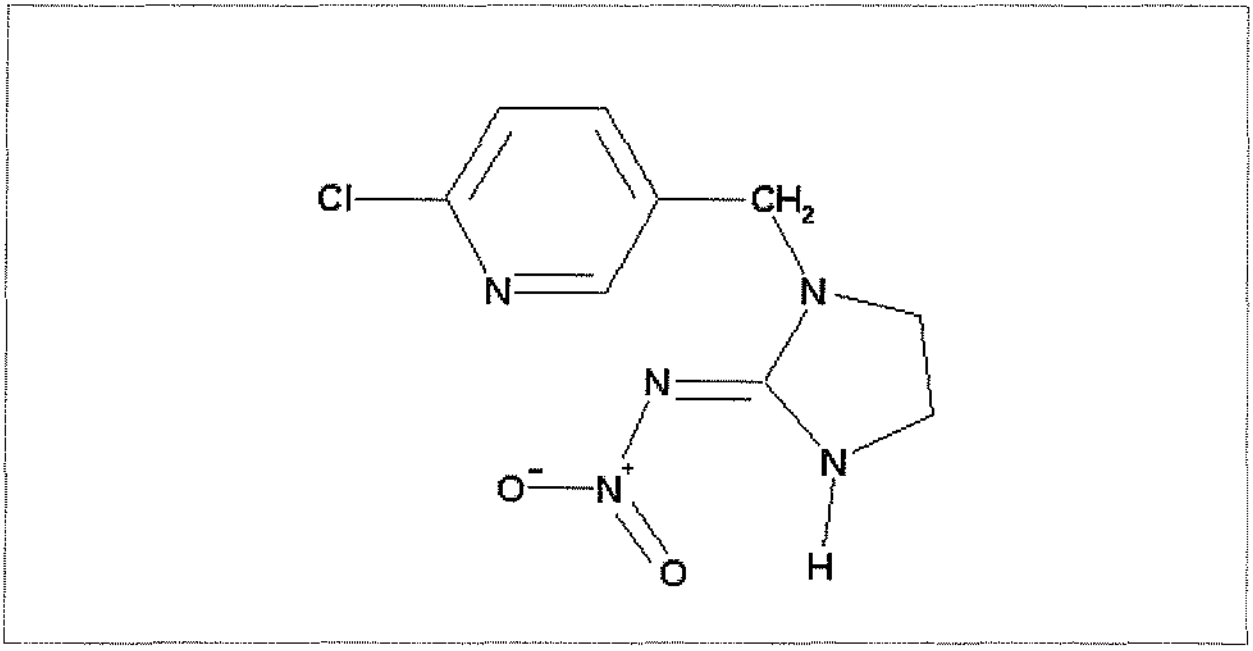
Uncertainties and Additional Data Needs

There are a number of uncertainties that translate into data needs related to the proposed use of imidacloprid on shellfish beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and overlying water. Furthermore, while preliminary data have been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of vegetation, pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro (guanidine), and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro (guanidine) metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

United States
Environmental Protection
Agency

IR4 Petition for the Use of Imidacloprid on Shellfish Beds in Willapa Bay and Grays Harbor, State of Washington (PC 129099); D399685, 399877, 399882



Date: 03/13/13 *Prepared by:* Joseph DeCant, Ecologist Michael Barrett, Senior Chemist	*U. S. Environmental Protection Agency* *Office of Pesticide Programs* *Environmental Fate and Effects Division* *Environmental Risk Branch IV*
Approved by: Mah Shamim, PhD, Branch Chief	*1200 Pennsylvania Ave., NW* *Mail Code 7507P* *Washington, DC 20460*

Contents

Executive Summary

IR4 requests registrations for the uses of Protector 2F and 0.5G (imidacloprid as the active ingredient) for the control of ghost and mud shrimp on shellfish beds in Willapa Bay and Grays Harbor, Washington. The proposed labels for Protector 2F (flowable concentrate) and 0.5G (granular) allow for one application of imidacloprid at 0.5 lb a.i./acre per year.

The primary organisms of concern due to direct toxicity from both acute and chronic exposure are the benthic and free-swimming estuarine/marine invertebrates. The use of the flowable and granular formulations presents a risk that exceeds all LOC's at onsite locations on an acute basis for free-swimming invertebrates and benthic invertebrates that inhabit the sediment. In terms of chronic exposure, the RQ's exceed the LOC's at onsite locations for both flowable and granular formulations for benthic invertebrates. Free-swimming invertebrates are also at risk due to chronic exposure on the site of application. In contrast to modeling results, the submitted monitoring report indicates that the overlying water contains very little parent imidacloprid at 21 days post application and would likely not impact free-swimming invertebrates in the overlying water following chronic exposure. These data have not been formally submitted, represent only a partial submission of collected data, and have not been reviewed by EFED. Consequently there is uncertainty in any conclusions drawn from this data. In addition, according to modeling estimates (including partition modeling of concentrations in shallow tidal water from sediment pore water data), low residues of imidacloprid or its degradates in overlying water, as well as pore water, can persist weeks after applications. Therefore, there is uncertainty in the comparison of the overlying water and pore water concentrations over time related to aquatic invertebrate toxicity. Aquatic invertebrate taxa represent the base of the food chain, and impacts on these taxa will likely cascade up the food chain, resulting in a reduction in prey and modification of PCE's related to endangered species due to fewer prey, as highlighted in the conceptual diagram in **Figure 1**. Additionally, direct effects on these individual organisms, including crab species, can also be expected. Recruitment of other individuals to on-site locations following removal of the shrimp may be a significant pathway of recovery for the impacted taxa. However, the submitted biotic monitoring data indicate potential decreases in abundance for crustaceans and polychaetes at least 28 days post application without evident recovery, although these results are uncertain as well because the data are partial or incomplete and have not been formally submitted for review. Nonetheless, the submitted biotic monitoring data support the aquatic invertebrate risk conclusions contained in this assessment.

While EFED recognizes that acute mortality in the immediate application site may be very high for aquatic animals trapped in tide pools and/or living in benthic sediments, the potential for off-site effects and overall impact to Willapa Bay as a whole appears limited. This is based on estimates that roughly 10% of the total acres (79,000 total acres) of the bay are under shellfish production during any given year, the label allows only one application per year, relatively low or non-detectable residue levels at 30ft off-site, and that during a complete tidal cycle (low tide to high tide), as much as 25.4 million ft^3 of water (up to 45% of the bay's total volume) may be exchanged. Thus, the opportunity for dilution alone is significant. Although this discussion has focused primarily on Willapa Bay, it is believed that the same potential for dissipation exists for Grays Harbor where a similar percentage of the total acreage may be treated. However, EFED also notes that the potential acreage to which imidacloprid will be applied may increase if

recruitment rates of ghost and mud shrimp increase. Sustained increases in the acreage treated may be accompanied by increases in the spatial extent of consequent long-term impacts to the aquatic invertebrate assemblage (and an increased potential for indirect effects to taxa that depend on these invertebrate species) for the following reasons:

- The persistence of imidacloprid in sediment pore water for weeks after the initial application
- The sensitivity of certain marine taxa to imidacloprid
- The results from the risk assessment showing acute and chronic LOC exceedances for estuarine free-swimming and benthic invertebrates
- The preliminary indication that chronic effects are possible that reduce abundance of polychaete and crustacean taxa on the site of application at least up to 28 days post application without apparent recovery
- Environmental fate studies in soil and soil-water systems indicate that imidacloprid residues may persist for hundreds of days following application suggesting that imidacloprid might remain present in the estuaries from year to year (even though concentrations in most collected samples fall below detection limits after only 1 year's application to limited acreage)

It is also important to note that these impacts are primarily on the site of application with little concern off-site. Uncertainty remains regarding the risk picture off-site due to yearly applications of imidacloprid to the same oyster beds, potential increases in the acreage to which imidacloprid will be applied, and the persistence of imidacloprid residues in the sediment pore water where the concern is that residues may remain available or increase off-site over time. Consequently there is uncertainty in the spatial extent of the residues and potential impacts off-site.

In terms of terrestrial taxa, risk is only present for the flowable formulation but not the granular formulation. For the granular formulation (Protector 0.5G), the avoidance behavior exhibited by birds, the unlikely consumption of granules by larger mammals feeding in the mudflats, and the requirement that the granules dissolve on the mudflats to lead to surface residues leads EFED to conclude that the granular use on exposed or inundated mudflats will not pose a risk concern for terrestrial taxa. For the flowable formulation (Protector 2F), EFED found no risk to mammals, and the risk to birds appears to be for applications of Protector 2F at low tide to exposed mudflat surfaces. Similarly, the concern for terrestrial invertebrates other than bees also relates to the same application of Protector 2F to exposed mudflat surfaces. In summary, only applications of Protector 2F to exposed mudflat surfaces with or without vegetation (*e.g.*, eelgrass) pose a risk concern to terrestrial taxa, but this risk persists for a relatively short amount of time as inundation is expected to rapidly dilute the residues of imidacloprid. Based on preliminary data, this risk concern could be addressed by limiting applications of Protector 2F to periods when there is standing water over the mudflats. The data do not definitively answer the question of how much water should be on the bed though because measurements on eelgrass were not taken at various times immediately after application, but rather at 24 hours after application at the earliest time. The additional monitoring data that have yet to be submitted to the Agency may address this question.

Additional Data Needs

There are a number of uncertainties that translate into data needs related to the proposed use of imidacloprid on shellfish beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and overlying water. Furthermore, while preliminary data has been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of vegetation, pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro (guanidine), and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro (guanidine) metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

Problem Formulation

Commercial shellfish beds in Willapa Bay and Grays Harbor, Washington, are important sources of shellfish production in the United States. In order to maintain the productivity of these beds for shellfish production, growers need to control various species of burrowing shrimp. Two native crustacean species, the ghost shrimp, *Callianassa* sp., and the mud shrimp, *Upogedia* sp., burrow into the sediment of the bays and disturb shellfish habitat (Felsot and Ruppert, 2002)[1]. To date, these burrowing shrimp have been managed using applications of carbaryl. However, the voluntary phase-out of carbaryl use in these estuarine habitats for controlling the burrowing shrimp has provided the impetus for the search of an alternative means of controlling these shrimp.

In response to this search, the Oyster Growers Association of Willapa Bay and Grays Harbor have explored the use of imidacloprid on these commercial shellfish beds. Small scale research trials were initiated in 2005 to explore the efficacy of imidacloprid to control burrowing shrimp. Then in 2008 through 2012 large scale trials were conducted not only to evaluate the efficacy of imidacloprid but also to explore the fate of the chemical in the estuarine systems and the potential for adverse effects to the ecological integrity of the biological communities. Monitoring of residues and effects data from these past studies have been submitted to the Agency through 2010; however, only a summary of the 2011 monitoring data and none of the 2012 data from the most recent experimental use permits have been submitted to the Agency for review. When available, analysis of the additional data for 2011 and 2012 might provide an improved understanding of imidacloprid environmental fate and effects under the conditions of this use.

Following the conduct of these large scale studies under the experimental use permits, IR4 requests registrations for the uses of Protector 2F and 0.5G (imidacloprid as the active ingredient) for the control of ghost and mud shrimp. The proposed labels for Protector 2F (flowable concentrate) and 0.5G (granular) allows for an application of imidacloprid at 0.5 lbs a.i./acre per year.

Willapa Bay is located on the Pacific coast of Washington State and encompasses 79,000 acres at mean high tide representing a volume of 56.6 million ft^3 of water. The tidal range in Willapa Bay is from 14 to 16 feet and roughly 45% (25.4 million ft^3) of the water in the bay is exchanged into the Pacific Ocean during a complete tidal cycle. The relatively shallow bay has more than 50% of its acreage exposed at low tide with much of the remaining surface area, except for channels, covered by 1 to 6 feet of water. Channel depths range from 30 to 50 feet with maximum depths 75- to 77-ft below mean low water. Willapa Bay opens to the Pacific Ocean at its northwestern corner through a broad shallow pass about 6 miles wide between Cape Shoalwater and Leadbetter Point. Major tributaries to the bay include the Willapa River to the north and the Naselle River to the south, together draining an area of 461,280 acres in Pacific County, Washington. Rainfall in the Willapa Bay area ranges from 85 - 100 inches per year resulting in mean annual runoff for the entire basin of 3.4 million acre-feet; mean maximum discharge at the

[1] Felsot, A.S. and J.R. Ruppert. 2002. Imidacloprid residues in Willapa Bay (Washington State) water and sediment following application for control of burrowing shrimp. J Agric. Food Chem. 50:4417-4423.

mouth of Willapa Bay is estimated at 1.6 million ft^3/second. Mean daily runoff is estimated to be about 0.004% of the total volume of the bay (Hedgpeth, J. W. and S. Obrebski 1981. Willapa Bay: A Historical Perspective and a Rationale for Research. Coastal Ecosystems Project, Office of Biological Services, U. S. Fish and Wildlife Service FWS/OBS-81/03).

The entrance of Willapa Bay is approximately 28 miles north of the mouth of the Columbia River and approximately 11 miles south of the entrance to Grays Harbor. Flushing rates (tidal prism) in Willapa Bay are influenced by conditions in the ocean. During the summer, strong northwesterly winds bring upwelled water from the ocean into the bay and promotes rapid turnover. Strong Pacific storms also promote mixing. At other times though, freshwater outflow from the Columbia River acts as a discrete water mass moving northward along the Pacific coast and may prevent mixing from occurring in the bay (Hedgpeth and Obrebski 1981).

Imidacloprid {1 - ((6 - chloro - 3 - pyridinyl) methyl) - 4,5 - dihydro - N - nitro - N - nitro - 1H - imidazol -2-amine} is a systemic neurotoxic insecticide of the nitroguanidine chemical class (chlorinated derivative of nicotine). As a neuron effector, this compound attacks the cholinergic receptors, especially the nicotinic receptors, by out-competing acetylcholine for available binding sites, thereby rendering acetylcholine dysfunctional. In terrestrial systems, given its systemic properties in a plant, it typically kills feeding insects via ingestion or contact by disrupting the nervous system. In these estuarine systems, the imidacloprid may act by causing acute mortality or immobilization to the ghost and mud shrimp.

In light of the proposed use pattern on shellfish beds and direct application to the aquatic environment in estuarine systems, EFED focused its assessment primarily on the potential harm to aquatic organisms. The aquatic species exposure assessment did not directly use the PRZM/EXAMS model normally used for such assessments as it has not been designed to evaluate pesticide fate in estuaries / intertidal / subtidal waters. Rather, we used monitoring data already available for this use as well as conservative (protective) assumptions regarding imidacloprid fate in this environment with the understanding that imidacloprid behavior may be different in some ways in estuarine environments. Exposures in sediment pore water and in standing water directly over and near the application area were assessed. The surface / pore water assessment for this compound takes into consideration the proposed label, use patterns, application rates and methods of application. Data submitted from the Oyster Growers Association and data provided by the registrant (e.g., environmental fate and effects), and information gleaned from peer reviewed open literature, were all used to support the risk characterization. In order to evaluate potential concerns to birds and mammals that feed on exposed prey items, EFED also assessed birds and mammals that fed on contaminated prey using the Kow (based) Aquatic Bio-Accumulation Model (KABAM) as well as TREX using the contaminated arthropod data.

Although EFED does not conduct risk assessments on beneficial insects, available toxicity profiles (e.g., honey bee oral and contact toxicity studies), incident reports and proposed use patterns are taken into consideration in order to arrive at a best professional judgment as to potential risk to these organisms. The potential for direct toxic effects to honey bees is minimal given the low likelihood of exposure from the use pattern on oyster beds. However, EFED assessed potential effects to terrestrial invertebrates that may inhabit the tidal mudflats after

applications of imidacloprid.

The representative aquatic receptors are certain estuarine/marine fish, invertebrates, and, in certain cases, aquatic plants. The representative terrestrial receptors are mammals, birds, and invertebrates that feed in the intertidal mudflats where commercial shellfish are produced. It should be noted, that these species do not cover all the possible species in the animal and plant kingdoms; certain taxa are considered as surrogates for other taxa. Fish are considered surrogates for aquatic amphibians and reptiles, whereas birds are considered surrogates for terrestrial amphibians and reptiles.

The major point of exposure for aquatic organisms is direct contact with contaminated water or sediments (gill/ integument uptake), while for terrestrial invertebrates it is primarily through contact exposure to contaminated substrate. For terrestrial vertebrates, the primary routes of exposure are consumption of contaminated food items. A conceptual diagram (**Figure 1**) shows that various routes of exposure.

Risk Hypothesis:

The insecticide imidacloprid as proposed as a spray and granular product on shellfish beds involves situations in the environment where direct contamination of bodies of water are potential routes of exposure to aquatic taxa. Furthermore, these applications may result in exposure to terrestrial animals that feed on contaminated food items, come into contact via dermal exposure, or that may directly consume granules on the sites of application. Based on imidacloprid's persistence, mode of action, direct toxicity and potential indirect effects to trophic food webs, it is assumed that this compound may have the potential to cause reduced survival and possible reproductive impairment to both aquatic and terrestrial organisms on estuarine tidal mudflats in Grays Harbor and Willapa Bay, Washington.

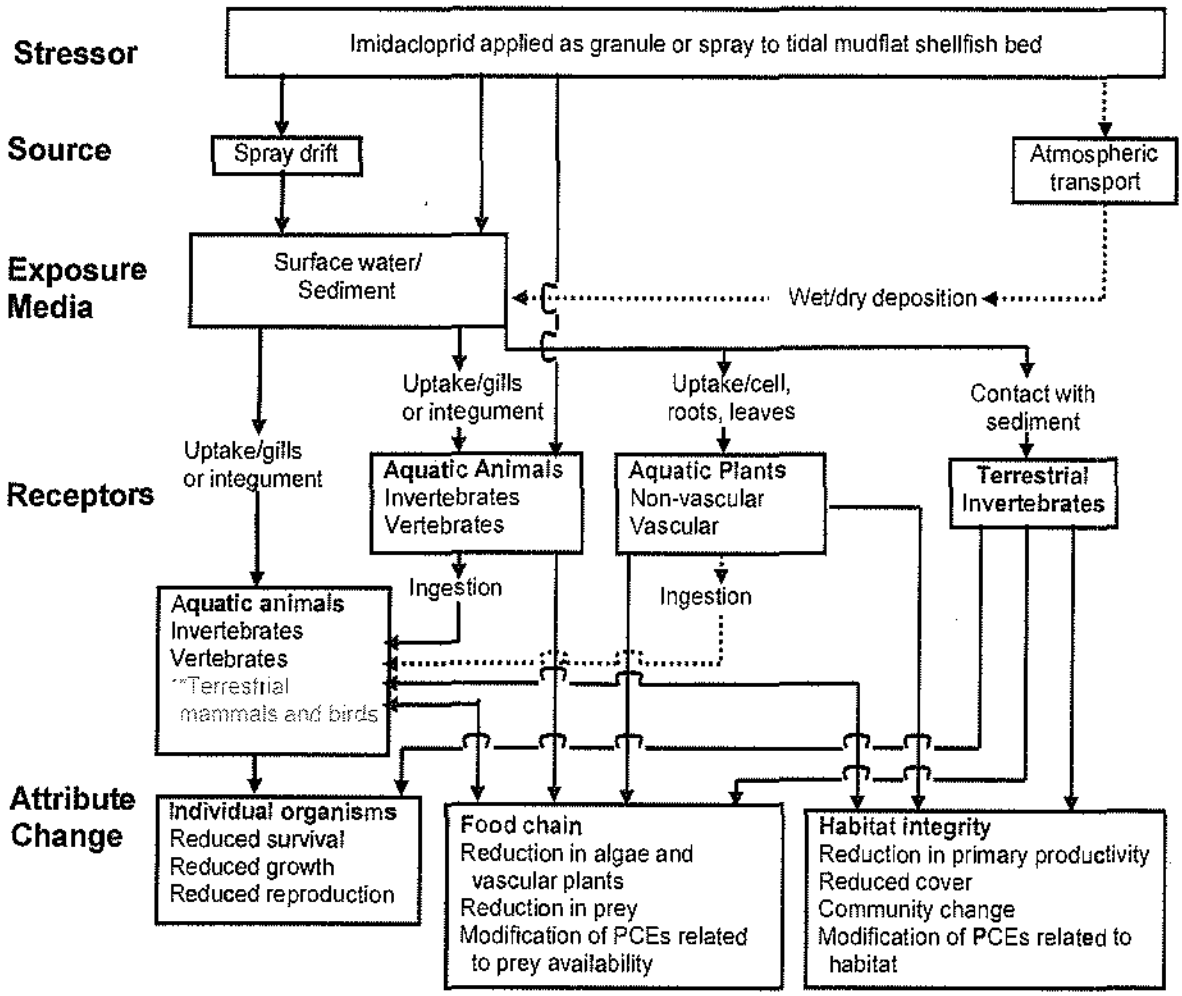


Figure 1. Conceptual model for the exposure pathway to aquatic organisms and terrestrial organisms that use the shellfish mudflats at low tide. Dashed lines represent pathways not considered to be significant due to the use pattern or chemical nature of imidacloprid.

Exposure and Effects Analysis

Analysis is a process that examines the two primary components of risk, which are exposure and effects, and their relationships between each other and site characteristics. The objective is to provide the ingredients necessary for determining or predicting ecological responses to pesticide use under exposure conditions of interest. The products of analysis provide the basis for estimating and describing risks in risk characterization.

Label Information

Product Names and Reg. Nos.: *Protector 2F (88867-E) and 0.5G (88867-R)*

Composition
Protector 0.5G
Imidacloprid (a.i.) 0.5%
Inerts 99.5%

Protector 2F
Imidacloprid (a.i.) 21.4%
Inerts 76.6%

Formulation and Use:
Protector 0.5G is a granular formulation of imidacloprid to be applied at a rate of 0.5 lb a.i./A as a single application per year, which must occur between April 15 and December 15. This product will be applied to control burrowing shrimp in intertidal shellfish beds of Washington State's Willapa Bay and Grays Harbor. Application equipment includes conventional granular pesticide applicators ("belly grinders"), helicopters equipped with a boom ¾ as long as rotor diameter, or a ground based vehicle equipped with spinners or drop spreaders. Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.

Protector 2F is a flowable formulation containing 2lbs of imidacloprid per gallon of product to be applied at a rate of 0.5 lb a.i./A as a single application per year, which must occur between April 15 and December 15. This product will also be applied to control burrowing shrimp in intertidal shellfish beds of Washington State's Willapa Bay and Grays Harbor. Application equipment includes helicopters equipped with a boom ¾ as long as rotor diameter and equipped with Accuflo or similar nozzles, or a backpack sprayer, or ground based vehicle with a boom. A single application per year is allowed. Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.

Label Warnings
The following environmental hazards statements are currently on the proposed labels for 0.5G and Protector 2F:

Protector 0.5G: *Do not contaminate water when disposing of equipment washwaters. This product is toxic to wildlife and highly toxic to aquatic invertebrates.*

Protector 2F: *Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops and weeds. Do not allow this product to drift to blooming crops or weeds are visiting the treatment area. This product is toxic to wildlife and highly toxic to aquatic invertebrates.*

Environmental Fate Summary

Imidacloprid degrades most rapidly when subjected to aqueous photolysis and/or anaerobic aquatic metabolism. Imidacloprid appears to be stable (persists for several months or more) to aerobic soil metabolism. The chemical is mobile and because it is also highly persistent, is a major concern for groundwater where there have been detections. Its transformation product imidacloprid guanidine / desnitro may also leach to groundwater. Imidacloprid may readily runoff dissolved in water and reach adjacent bodies of water. Since the chemical appears to be persistent under aerobic soil metabolism, imidacloprid may be available for runoff for periods exceeding one season.

It appears that photolysis plays an important role in the environmental dissipation of imidacloprid if it is exposed to sunlight, both in aqueous solution (half-life 0.2 days) and on soil (half-life 39 days). In aqueous solution, the degradates imidacloprid guanidine / desnitro (17% at 2 hours; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}) and imidacloprid urea (10% at 2 hours; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone.{NTN 33519}) were observed. However, the length of the study did not allow for observation of the stability of the degradates; furthermore, there is uncertainty regarding this study because other laboratory studies were performed under sunlight and no extensive degradation of the parent was observed. Another route of transformation that appears to be important for imidacloprid is anaerobic aquatic metabolism (half-life 27 days), with the formation of imidacloprid guanidine / desnitro (66% at 249 days; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}), a compound that appeared to be very persistent.

In a domestic sandy loam, and foreign loamy sand, silt loam, and sandy loam, imidacloprid proved to be very persistent under aerobic soil metabolism conditions. The respective half-lives were 660, 188, 248 and 341 days. No major transformation products were detected in these studies.

Imidacloprid has K_{OC}s ranging from 161 to 256 (based on nine soils, five domestic and four foreign). The K_{ads} range is 0.96-4.76 for the same nine soils. Imidacloprid guanidine / desnitro is somewhat less mobile than the parent imidacloprid (K_{OC} range 327-942; K_{ads} range 0.76-14.20).

Due to the very low octanol/water partition coefficient of imidacloprid, it is not expected to bioaccumulate in fish and the data requirement was waived.

Five terrestrial field dissipation studies confirm the findings in the laboratory, that under aerobic soil metabolism conditions, imidacloprid persists substantially. The dissipation half-lives from topsoil were as follows: >365, >>365, 146, 107, and >120 days.

Small scale prospective ground water monitoring (PGW) studies in Michigan and California have been conducted, and while not necessarily representing field conditions under which ground water recharge and imidacloprid leaching would be greatest, do provide some information on imidacloprid leaching and ground-water contamination potential. Imidacloprid and some of its degradates were shown to leach in soil during water infiltration periods at both

study sites.

The California study appears to include some effects of nearby applications of imidacloprid in years prior to the initiation of the study, with control samples bearing imidacloprid residues. At the California site only a few ground-water detections of imidacloprid and its degradates have been reported at concentrations between 0.05 and 0.10 ppb. The study does demonstrate that imidacloprid may leach substantially under conditions of irrigated agriculture for vegetable crops in California.

In the Michigan study (planted to potatoes), imidacloprid (applied once at a 0.34 lb a.i./A rate) leached at a variable rate and concentration. Detectable residues of imidacloprid occurred in six out of six, and in four out of six on-site lysimeters at the three and six foot depths, respectively, by 319 days after treatment (DAT 319), at concentrations up to 3.35 ppb.

At the Michigan study site, imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period (there were a few detections before application that may have been due to previous uses nearby or sample contamination). The maximum concentration of imidacloprid parent detected in ground water in any one sample at the Michigan study site was 0.24 ppb. EPA concluded that the 0.24 ppb level might increase slightly over time as imidacloprid continues to leach into groundwater; however, the level was not expected to increase dramatically given that the levels seen at the three and twelve foot soil depths was 1.63 ppb and 1.31 ppb, respectively.

Data from the California site is less useful due to the fact that there appears to have been very little ground-water recharge occurring during the course of the study as evidenced by the almost complete lack of detection of the bromide tracer (applied concurrently with imidacloprid) in ground water. The maximum combined residue of imidacloprid parent and degradates found in the suction lysimeters was 0.62 ppb at 633 days post application (made once at a rate of 0.45 lb a.i./A). The maximum combined imidacloprid residue in the ground water at the California site was 0.14 ppb found 149 days post application. EPA concluded that low (sub-ppb) level contamination of potable ground water might occur in this region following application to irrigated vegetable or fruit crops.

Other significant ground-water monitoring data[2] include evidence of leaching of imidacloprid from New York state monitoring. Suffolk County Department of Health Services reported that there were 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 samples.[3]

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[2] An updated review of the available monitoring data may be conducted if a permanent registration of this new use is sought.

[3] Electronic mail communication from Sy Robbins, Suffolk County Department of Health Services, Bureau of Groundwater Resources), 1/16/2004 to Michael R. Barrett, (US EPA, Office of Pesticide Programs Environmental Fate & Effects Division). See also:

More recently, imidacloprid has been detected in several domestic drinking water wells in New York State:

> "To date, imidacloprid has been detected at concentrations (0.2 to 7 ppb) in 12 monitoring wells and 16 down gradient private homeowner wells. Imidacloprid has also been recently detected at 0.24 ppb in two Suffolk County community water supply wells (85 feet and 90 feet deep)." (Imidacloprid NYS DEC Letter - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04)

Not all of the imidacloprid detections in drinking water wells, however, necessarily represent normal leaching from an imidacloprid-treated field (See **Appendix A** for details).

In a small turf plot surface water runoff monitoring study by the registrant, the plot received from 1.7 to 3.5 in. water per hour for two hours. Up to 20% of the applied imidacloprid was found in runoff water 24 hours after application.

Fate Assessment for Exposure Modeling

Imidacloprid is stable to hydrolysis, and typically persists for many months in soil. However, imidacloprid appears to be more rapidly transformed under anaerobic conditions and appears to be particularly photolabile in pure, clear, shallow water. Given that imidacloprid is mobile, and likely to be highly persistent in the subsurface, it may leach to ground water (results of the prospective ground-water monitoring studies confirm this). Imidacloprid may also pose a contamination hazard to surface waters via runoff, and may be especially persistent in surface water with high turbidity.

The environmental fate for imidacloprid is discussed in more detail in **Appendix A**.

EFED concludes that the available data on imidacloprid show that the compound is mobile and persistent, and, for the terrestrial uses, has potential to leach to ground water, and to be transported to surface water by runoff. In the context of the proposed use in estuaries, the available fate data would seem to indicate that at least some portion of the applied imidacloprid may be adsorbed to sediment and resistant to long-term degradation (similar to what has been observed in terrestrial field dissipation studies. However, no studies are available on the fate of imidacloprid in salt water / estuaries. No direct environmental fate studies have been conducted for the degradates {several of which retain the (pyridinyl)methyl-imidazoli-amine backbone of

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Bradley, Clare B.; Vito Minei, and Martin Trent. 2002a. *Golf course impacts to shallow groundwater: Suffolk County, NY.* Suffolk County Dept. of Health Services & Bureau of Groundwater Resources report received in a personal communication from Martin Trent, February, 2004. (No report number assigned).

Bradley, C.B.; V. Minei, and M. Trent. 2002b. *Impacts of agriculture on shallow groundwater in Suffolk County, NY.* Suffolk County Dept. of Health Services, no document or report number assigned.

Bradley, C.B.; V. Minei, M. Trent, and S.F. Robbins. 2003. Water quality monitoring program to detect pesticides in groundwaters of Nassau and Suffolk Counties, NY: Monitoring conducted April 2001 - March 2002. Suffolk County Dept. of Health Services, no document or report number assigned.

the imidacloprid molecule}, including the following (potentially) major environmental degradates typically found under aerobic conditions: 1) imidacloprid guanidine / desnitro, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}; 2) imidacloprid olefin, 1-[(6-chloro-3-pyridin1yl)methyl]-1,3-dihydro-2H-imidazol-2-imine {NTN 35884}; and 3) imidacloprid urea, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone{NTN 33519}. Under anaerobic conditions, imidacloprid is reduced to the guanidine / desnitro and then to 6-Chloronicotinic acid {BNF 5518A}[4]. See **Appendix B** for chemical structures of these degradates. Another metabolite of imidacloprid in some biological systems and of some toxicological concern (discussed later in this review), imidacloprid nitrosiamine, has not been reported to any significant extent in environmental fate studies.

Terrestrial Exposure Estimation

Measures of exposure for terrestrial invertebrates directly exposed to spray applications or mammals and birds that feed on plants or invertebrates in the tidal mudflats incorporate maximum proposed use rates, but rely less on environmental fate properties. Terrestrial exposures were estimated using a number of methods. The Kenaga nomogram, as modified by Fletcher *et al.*, (Kenaga and Hoerger 1972; Fletcher *et al.* 1994) is used to relate pesticide application rates to chemical residues on terrestrial food items. The surface residue concentration (in parts per million; ppm) is estimated by multiplying the application rate (pounds active ingredient per acre; lbs a.i./A) by a value specific to each food item. The Terrestrial Exposure (T-REX; version 1.5.1) model is used with the maximum application rates on the proposed labels. Acute exposure is the only type of exposure considered in this assessment so degradation is not considered because of the tidal nature of the system. Tides remove much of the residues considering the solubility of imidacloprid. The conceptual approach taken to estimate residues (upper-bound and mean) in potential dietary sources for mammals and birds is presented in the model T-REX Version 1.5.1 available at:

http://www.epa.gov/oppefed1/models/terrestrial/index.htm

In addition, the model KABAM (Kow(based) Aquatic BioAccumulation Model, ver.) was used in this assessment to quantitatively assess the risk of imidacloprid to birds and mammals that feed on aquatic food sources contaminated through bioaccumulation. While imidacloprid has a very low Kow, which suggests very low potential exposure levels, KABAM provides a quantitative confirmation of the risk expectations. Details on KABAM Version 1.0 are available at:

http://www.epa.gov/pesticides/science/models_pg.htm#aquatic

Aquatic Exposure Estimation

In this assessment, measures of exposure are made with a combination of analysis of available imidacloprid residue monitoring data and assumptions on degradation and partitioning rates from

[4] Preliminary information from MRID 48416901 (Wilmes, R. 1988. Aerobic aquatic metabolism of NTN 33893); study is still under review, however. Imidacloprid guanidine / desnitro was the dominant primary degradate in studies from both MRID 42256378 and MRID 48416901.

the available environmental fate data (there are only a limited amount of such data, however, directly examining imidacloprid fate in salt water). Generally, aquatic exposure estimates are generated from EFED models and incorporate maximum proposed use rates and empirically-derived fate properties. However, currently approved aquatic exposure models for EFED (e.g., PRZM-EXAMS, GENEEC) are not designed to estimate exposure in estuarine environments. Partitioning theory that is incorporated into such models was used along with the available environmental fate data to conservatively estimate exposure of organisms to imidacloprid residues in both sediment pore water and tidal flood waters. Additional details on exposure estimation procedures and model inputs and outputs are provided in **Appendix C**.

A summary of model input parameters for imidacloprid used in the modeling is provided in **Table 1**. Exposure to degradates was also estimated, but only as part of the total imidacloprid residues. Estimation of exposure to individual degradates (like the potentially more toxic desnitro olefin as based on EcoSAR estimates) is not feasible given that both environmental monitoring and fate data are limited in terms of capturing the full extent of formation and decline of the degradates. However, for the two degradates of potential toxicological concern, the available fate data imply that, except in anaerobic sediments/soils, the olefin could potentially be a major component of exposure over time whereas the nitrosamine would likely not be (except for organisms consuming other organisms which have already converted imidacloprid to the nitrosamine.)

Table 1. Imidacloprid parent environmental fate parameters utilized in oyster bed exposure assessment.

Parameter	Input	Source
Solubility (ppm)	580	Product chemistry submissions
Hydrolysis $t_{1/2}$ @ pH 7 (days)	Stable	MRID 42055337
Aerobic soil $t_{1/2}$ (days)	520	MRIDs 452393-01, 02, 42073501; 90% upper bound confidence limit of mean
Aerobic aquatic $t_{1/2}$ (days)	165 (prelim.)	MRIDs 48416901 and 48416902; 90% upper bound confidence limit of mean (preliminary value – studies are still in review.)
Photolysis $t_{1/2}$ in soil or water (days)	39 (soil) 0.2 (water)	Input guidance & MRIDs 42256376; 42256377; the longer soil photolysis values is considered more relevant to this assessment because of persistence in irradiated water in ecotoxicity studies (inconsistent with a 0.2 day $t_{1/2}$ value) and limited exposure of imidacloprid molecules to sunlight from the oyster bed use.
Organic carbon partition coefficient		

- K_d (mL/g)	0.5, 1.0, or 3.0	MRIDs 425208-01 and 420553-38 and Felsot and Ruppert (2002).
Application rates (lb a.i./Acre)	0.5	Maximum on proposed label.
Applications / year Oyster Beds	1	Maximum on proposed label.

Sediment Pore-Water Exposure.

Acute and chronic (for durations up to 35 days) estimated environmental concentrations (EECs) for benthic invertebrates and other organisms feeding in areas where they would be exposed to concentrations in the sediment pore water are presented for the granular and flowable formulations in **Table 2** and **Table 3**, respectively. These time-weighted exposure estimates are based upon 90th percentile upper bound confidence limits of the mean concentrations detected over time in a 2010 monitoring program for the Oyster Growers Association of Willapa Bay and Grays Harbor, adjusted for the currently proposed maximum application rates and other factors. The total residue estimates conservatively assume that all of the residues detected with the enzyme-linked immunosorbent assay (ELISA) analysis represented degradation products of imidacloprid such as imidacloprid olefin, desnitro imidacloprid (guanidine degradate), or imidacloprid urea which have been shown to be detectable by the method used.

For the flowable formulation the initial concentrations detected in the soil pore water after application were close to theoretical concentrations assuming all of the applied imidacloprid was in the top 10 cm of sediment pore water (the sampling depth used). For the granular application the concentrations were significantly below expectations. The slower release of imidacloprid from the granular formulation may have contributed to the lower concentrations detected initially, but it is also true that observed concentrations continued to be lower from the granular application than from the flowable application over time.

Table 2. Estimated ecological concentrations (EECs) in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, granular formulation.)

Moiety	Crop Scenario	Peak (theoretical)	Peak (measured)	Acute (24-hour)	21-day	35-day
Parent	Oyster Bed On-site	1252.5	221.2	97.0	9.9	6.3
Total Residues	Oyster Bed On-site	1252.5	221.2	97.0	30.8	19.7
Total Residues	Oyster bed off-site*	NC	0.8	0.8	0.5	0.4

Values in this table are time-weighted average exposure levels for the specified duration of exposure based upon time weighting upper bound Confidence Limits of mean of on-site or off-site detections at each sampling interval. For off-site chronic exposure, residues at just below the limit of detection were assumed when no detections were reported

Table 3. Estimated ecological concentrations (EECs) in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, flowable formulation).

Moiety	Crop Scenario	Peak (theoretical)	Peak (measured)	Acute (24-hour)	21-day	35-day
Parent	Oyster Bed	1252.5	1066.4	416.8	34.3	21.8
Total Residues	Oyster Bed	1252.5	1066.4	416.8	107.1	68.1
Total Residues	Oyster bed off-site*	NC	2.0	2.0	1.6	ND

Values in this table are time-weighted exposure levels for the specified duration of exposure based upon time weighting upper bound Confidence Limits of mean of on-site or off-site detections (proportionally adjusted from the original 2.0 to a 0.5 lb a.i./A application rate) at each sampling interval.

The significant decrease in chronic EECs from acute EECs reflects a rapid decline in the observed concentrations over time (see **Table 4**, which shows the decline in point-in-time concentrations up to 28 days after the flowable application). This decline rate likely only partially reflects degradation and could be largely a function of dispersion of imidacloprid (since the available environmental fate data indicate imidacloprid parent may persist for several months or longer in the environment). Imidacloprid metabolites appear to represent an increasing percentage of the residues detected in the later times [based on preliminary data comparing HPLC (high-performance liquid chromatography) and ELISA (the enzyme-linked immunosorbent assay) analyses submitted by the registrant, a complete report has not yet been submitted].

Table 4. Instantaneous measured and estimated concentrations over time in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, flowable).

Moiety	*Crop Scenario*	*0 (theoretical)*	*0 (measured)*	*1 DAT*	*14 DAT*	*28 DAT*
Parent	Oyster Bed	1252.5	1066.4	40.1	3.9	3.1
Total Residues	Oyster Bed	1252.5	1066.4	40.1	12.1	9.7
Total Residues	Oyster bed off-site*	NC	1.3*	0.8	0.12	<0.1

All values are 90 percentile Upper Confidence bound of mean of detects at the specified time interval.
Off-site values are 90 percentile Upper Confidence Limit of mean of quantifiable detects 30 feet from the treatment area (either up- or down-gradient.) Original monitoring data were from a 2.0 lb a.i./A application; the values were adjusted proportionally downward to compare with the proposed 0.5 lb a.i./A maximum application rate.
* Value at 12 hours after application; residues not detectable at 30 feet off-site at the time of application. The highest single detect 30-feet from the treatment area.

Standing-Estuarine Water Exposure

Data on imidacloprid residues in standing tidal water over and near oyster beds are limited but tend to show low to nondetectable imidacloprid residues within a few hours or days after

application. However, there are some important factors that limit the ability of such sampling to accurately capture all residues remaining at the site:

- Residues of imidacloprid tend to increasingly associate with adsorbing materials in the sediment. Some of these residues may become "bound" and will not be detected except with particularly vigorous means to extract them.[5]
- Most studies do not include analyses of all degradates, which might contribute to imidacloprid toxicity to some organisms (cross-reactivity of the ELISA method with degradates formed over time might account for the relatively high chronic exposure estimates obtained from the 2010 soil pore water sampling program for the WGHOGA).

In order to assess the exposure potential of aquatic organisms present in shallow standing tidal water areas, we incorporated partitioning theory used in existing EFED aquatic exposure models (PRZM-EXAMS, GENEEC). Details of the procedure for these estimates are provided in **Appendix C**.

A comparison of directly measured concentrations of parent imidacloprid (specific monitoring data are not available for imidacloprid degradates) in standing tidal water from 2011 monitoring (HPLC analysis) with the calculated potential concentrations in standing water (based on distribution of the known concentrations in sediment pore water from the 2010 monitoring) is provided in
Table 5. This table provides insight into how modeling standing water concentrations compare with field measurements. Note that application rates in these studies may vary and that in some cases imidacloprid may have been present in field samples at levels below the reporting limit of the analytical method used. The modeled K_ds represent a range of potential adsorption coefficients for the sediment that are within the range of values previously reported for imidacloprid in soil[6]. Felsot and Ruppert (2002) examined the characteristics of sandy sediment in a small plot study of imidacloprid dissipation in Willapa Bay and found that it had a K_d of 0.37 and particle distribution of 84% sand, 15% silt, and 1% clay.
Table 5 shows the increasing trend in imidacloprid water concentrations when the sediment capacity to adsorb imidacloprid is lower (i.e., lower K_d), when the sediment mixing depth is shallower, and when the height of the standing water is shallower[7].

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[5] See, for example:
Cox, L.; Koskinen, W.; Yen, P. 1998. Changes in Sorption of Imidacloprid with Incubation Time. Soil Science Society of America Journal 62(2): 342-347.
Koskinen, W.; Cox, L.; Yen, P. 2001. Changes in Sorption/Bioavailability of Imidacloprid Metabolites in Soil with Incubation Time. Bioi Fertil Soils 33: 546-550.
Papiernik, S.K., Koskinen, W.C., Cox, L., Rice, P.J., Clay, S.A., Werdin-Pfisterer, N.R., Norberg, K. 2006. Sorption-Desorption of Imidacloprid and Its Metabolites in Soil and Vadose Zone Materials. J. Agric. Food Chem. 54(21):8163-8170.
[6] Imidacloprid adsorption / desorption properties have been measured in eight soils in the registration guideline studies to support its registration (MRIDs 42520801 and 42055338). In these studies Kd values ranged from 1 to 5 with a large amount of the variation in adsorption associated with the variation between soils in percent organic carbon (the Koc values only varied between 132 and 256 for the eight test soils).
[7] The available sediment pore water monitoring data only provide overall concentrations of imidacloprid residues in the sediment to a depth of 10 cm, it is not known whether most of the imidacloprid residues were present to a depth substantially less than 10 cm, hence the use of the 3 cm mixing depth as a conservative modeling scenario which would result in predictions of higher standing water concentrations of imidacloprid residues than if the mixing depth

Table 6 presents a summary of acute and chronic EECs (for parent imidacloprid only) for organisms residing in the standing water for exposure durations from less than 1 day to 35 days (these are time-weighted exposure values whereas values in
Table 5 are point-in-time concentrations). A sediment K_d of 1.0 ml/g (lowest value in guideline batch equilibrium adsorption / desorption studies) was chosen for these estimates in finer sediment and 0.5 ml/g in sandy sediment, the latter based upon the published study by Felsot and Ruppert (2002). Calculation of time-weighted ecological exposure concentrations was based upon 3- to 10-cm depth standing water exposure estimates, providing a conservative estimate of exposure in the sense that average EECs in standing water will be lower than these estimates if concentrations were to be averaged over the entire tidal cycle. However, it is also not known whether pulses of higher exposure during the low water periods may be of similar toxicological significance to the steady exposure levels that are often used for testing of effects. The most conservative of the mixing assumptions for these estimates (i.e., that mixing of imidacloprid only occurs in a 3 cm deep band of sediment and that 3 cm of floodwater is the most relevant depth of standing water to calculate EECs) was used for acute and chronic EEC estimation.

Table 5. Comparison of measured and estimated concentrations over time in ppb for parent imidacloprid in standing water: Oyster bed, proposed IR4 use (flowable formulation, 0.5 lb a.i./ A rate, or adjusted for such a rate).

Site Info / Assumptions	K_d, ml / g	Sd. Mix. Depth, cm	H_2O Depth, cm	0-0.1 DAT	1 - 3 DAT	14 DAT	Reference
Finer sediment (estimated)	1	3	3	600.0	9.5 - 22.6	2.18	PRZM 3 manual
Finer sediment (estimated)	1	3	10	320.0	2.6 - 7.5	0.62	PRZM 3 manual
Finer sediment (estimated)	1	10	3	244.3	3.9 - 10.9	0.89	PRZM 3 manual
Finer sediment (estimated)	1	10	10	179.8	1.5 - 4.2	0.35	PRZM 3 manual
Loamy sand sediment (estimated)	0.5	3	3	871.8	13.8 - 38.9	3.17	PRZM 3 manual
Typical agric. Soil	3	3	3	267.6	2.2 – 6.3	0.52	PRZM 3 manual
2011 Cedar River – Flow.	2 hr sample with <10 cm water depth.			1100 - 1400	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Palix R. – Flowable	2 hr sample with 15 cm water depth.			4 - 89	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Cedar R. – Granular	0 hr sample with 30 - 90 cm water depth.			0 – 31	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Palix R. – Granular	2 hr sample with 16 cm water depth.			0 - 82	<1.5	----	2011 prelim. WGHOGA Rpt.

Source: Information sheet entitled "2011 Results Summary" (no author, report number, or other identifying information provided. Some of the results seem to be inconsistent with "preliminary" data provided in Moore and Tufts (2011).

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was 10 cm. Further details are provided in Appendix D.

Table 6. Time-weighted acute and chronic EECs based on estimated concentrations of parent imidacloprid in shallow tidal water for acute and chronic exposure durations (flowable formulation, 0.5 lb a.i./A rate); assume sediment K_d of 1 ml/g (finer sediment) or 0.5 (sandy sediment).

Site Info / Assumptions	Sedimt. Mixing Depth, cm	Ref. Water Depth, cm	Peak	1-Day	4-Day	21-Day	35-Day
Finer sediment	3	3	600.00	231.00	102.95	21.79	14.81
Finer sediment	10	3	244.57	94.15	41.97	8.88	6.04
Sandy sediment	3	3	**871.75**	**335.61**	**149.59**	**31.66**	**21.53**

Other Surface Water Monitoring Data

An updated comprehensive review of all available surface water monitoring data was not practical for this review and we also note that these data are all for residues in freshwater as no estuarine uses have previously been registered for imidacloprid. Reports on imidacloprid surface water monitoring have increased in recent years as improved analytical methods have become more widely available. A number of reports have indicated low-level imidacloprid concentrations in surface waters (usually well under 1 ppb, although exposure might be higher in smaller bodies of water in small watersheds with intensive imidacloprid usage):

Byrtus, G., A. Anderson, K. Saffran, G. Bruns, and L. Checknita. 2002. Determination of new pesticides in Alberta's surface waters (1999-2000). The Water Research User Group, Alberta Environment. http://www3.gov.ab.ca/env/water/reports/NewPesticidesInSurfaceWaters_1999_2000.pdf

Environment Canada. 2006 (Draft). Presence, levels and relative risks of priority pesticides in selected Canadian aquatic ecosystems. Summary of 2003-2005 surveillance results. Prepared by Canlox Environmental for the National Water Quality Monitoring Office, Environment Canada, Ottawa.

Murphy,C., J.P. Mutch, D. Reeves, T. Clark, S. Lavoie, H. Rees, L. Chow, L-A. Nunn, and D. Hebb. 2006. Multi-media pesticide monitoring programs in Prince Edward Island, New Brunswick and Nova Scotia, Final Project Report of 3-year monitoring program, 2003/04 – 2005/06. Environment Canada, Environmental Protection Branch, Charlottetown.

Struger, J., T. Fletcher, P. Martos, B. Ripley, and G. Gris. 2002. Pesticide concentrations in the Don and Humber River Watersheds (1998-2000). Environment Canada, Ontario Ministry of the Environment, and City of Toronto. 21 pp.

USGS. 2007. Hydrologic, Water-Quality, and Meteorological Data for the Cambridge, Massachusetts, Drinking-Water Source Area, Water Year 2005. Open-File Report 2007–1049; Reston, VA.

Smith, Kirk P. 2011. Surface-Water, Water-Quality, and Meteorological Data for the Cambridge, Massachusetts, Drinking-Water Source Area, Water Years 2007–08. USGS Open-File Report 2011–1077.

Hladik, Michelle L. and Daniel L. Calhoun. 2012. Analysis of the Herbicide Diuron, Three Diuron Degradates, and Six Neonicotinoid Insecticides in Water—Method Details and Application to Two Georgia Streams. USGS Scientific Investigations Report 2012–5206.

Ecological Toxicity

The toxicity of imidacloprid to aquatic and terrestrial organisms is summarized below. More detailed information can be found in **Appendix D**. The available literature for ecotoxicity shows a nearly complete database for imidacloprid. In addition to these sources, a number of studies have been submitted to Europe and have been incorporated into the European draft assessment of imidacloprid[8]. The reviews from these studies have been used in this risk assessment, and the list of these studies are in **Appendix E**.

Aquatic (Acute/Chronic Hazard Summary)

Imidacloprid is considered to be practically non-toxic to fish (freshwater and estuarine/marine) on an acute basis (LC_{50} = 83 to 163 ppm). Chronic NOAEC/LOAEC values for freshwater fish were calculated at 1.2/2.5 ppm with growth being the major endpoint affected. However, toxicity studies on aquatic invertebrates (freshwater and estuarine/marine) show that this compound is acutely very highly toxic to these organisms (EC_{50} = 0.037 to 0.115 ppm). Chronic effects (growth and movement) were noted in daphnids (NOAEC/LOAEC = 1.8/3.6 ppm) and in mysid shrimp (NOAEC/LOAEC = 0.0006/0.0013 ppm). It is therefore evident that aquatic invertebrates are the taxa of concern related to aquatic exposure.

In data submitted to EFSA[9] but not to the US EPA, there are other endpoints worth noting. The EFSA assessment identifies a 28 day water spiked study with the benthic invertebrate *Chironomus riparius* with both the TGAI and a formulated product. The TGAI showed an EC_{15} of 0.00225 ppm, and the formulated product showed an EC_{15} of 0.0027 ppm. Consequently, benthic invertebrates appear to be very sensitive to chronic exposure to imidacloprid. There is uncertainty in these endpoints though, because the Agency typically uses a no effect level as opposed to the EC_{15} that is regression based. In addition, it is unclear how these endpoints relate to saltwater benthic invertebrates. A NOAEC is available from the midge acute toxicity study that the registrant has already submitted to the Agency and exhibits the lowest endpoint of 1ppb based on survival. It is important to note that this endpoint is based on a study evaluating acute exposure as opposed to the effects related to chronic exposure. However, since the Agency has not received the benthic invertebrate chronic exposure studies, these studies cannot be formally reviewed. Given the uncertainties related to the use of an endpoint from a water spiked study with a freshwater invertebrate and a chronic endpoint from an acute study, in addition to mysid shrimp appearing to be the most sensitive of all invertebrate taxa, the endpoint for chronic toxicity to mysid shrimp will be used for both free-swimming as well as benthic invertebrates that live in or on the sediment.

A number of studies with some of the degradates have been submitted to the Agency and are currently in review (MRIDs 43946601, 43946602, 43946603, 43946604, 44558901). These studies include acute toxicity data on the desnitro, urea, and 6-chloronicotinic acid to *Hyallela*

[8] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005. Table 2.6-6

[9] *Ibid.* Germany 2005.

azteca and/or *Chironomus tentans*. EFED has conducted a preliminary review of these studies, and these data show that the desnitro (guanidine), urea, and 6-chloronicotinic acid degradates are less toxic than the parent compound by at least over an order of magnitude. If the final reviews of these data provide additional information that alters the conclusions in this assessment, then EFED will revise its risk assessment as appropriate. Summaries of the studies are as follows:

- MRID 43946601: This study explored the acute toxicity of the desnitro/guanidine degradate to *Hyallela azteca*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the desnitro degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 5.3, 10.7, 21.4, 42.7, and 85.4 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *H. azteca* was used in the study and individuals were 0 to 7 days old when collected three weeks prior to study initiation, consequently they were 14 to 21 days old at test initiation. Mean measured concentrations reported in the study were 5.6, 11.0, 22.1, 43.8, and 86.8 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed the following mortality: 10% in the controls, 0% at the 5.6, 11.0, and 22.1 mg a.i./L levels, 30% at the 43.8 mg a.i./L level and 95% at the 86.8 mg a.i./L level. Sublethal effects were found at the 11.0, 22.1, 43.8, and 86.8 mg a.i./L test levels. No sublethal effects were observed in the control and 5.6 mg a.i./L test levels. The study authors reported a 96-hour LC50 at 51.8 mg a.i./L.

- MRID 43946602: This study explored the acute toxicity of the desnitro/guanidine degradate to *Chironomus tentans*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the desnitro degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 0.1, 1.0, 10.0, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study at the 2nd instar stage. Mean measured concentrations reported in the study were 0.12, 0.87, 8.19, and 82.8 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed the following mortality: 15% in the controls, 15% at the 0.12 mg a.i./L level, 0% at the 0.87 and 8.19 mg a.i./L levels and 15% at the 82.8 mg a.i./L level. Sublethal effects (mottled coloration and erratic behavior) were found at the 8.19 and 82.8 mg a.i./L test levels. No sublethal effects were observed in the control, 0.12 and 0.87 mg a.i./L test levels. The study authors reported a 96-hour LC50 at 17.0 mg a.i./L.

- MRID 43946603: This study explored the acute toxicity of the urea degradate to *Hyallela azteca*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the urea degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 6.25, 12.5, 25, 50, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *H. azteca* was used in the study and

individuals were 7 to 21 days old at test initiation. Mean measured concentrations reported in the study were 5.81, 11.80, 23.46, 46.80, and 94.83 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed very little mortality where one test organism died at 72 hours in the 94.83 mg/L level and 2 were missing (assumed dead) in control replicate A after 96 hours. No sublethal effects were found at any test concentration. The study authors reported a 96-hour LC50 at >94.83 mg a.i./L.

- MRID 43946604: This study explored the acute toxicity of the urea degradate to *Chironomus tentans*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the urea degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 0.1, 1.0, 10.0, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study and individuals were from 12 to 14 days old. Mean measured concentrations reported in the study were 0.10, 1.00, 10.04, and 99.80 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors reported very little mortality where one test organism died at 96 hours in the control and 100 mg a.i./L test levels. No sublethal effects were found at any test concentration. The study authors reported a 96-hour LC50 at >99.80 mg a.i./L.

- MRID 44558901: This limit test study explored the acute toxicity of the 6-chloronicotinic degradate to *Chironomus tentans*. The study employed a 96 hour static renewal design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the 6-chloronicotinic acid degradate were made using non-radio labeled test substance. Nominal concentrations for the test included a control and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study and individuals were aged at 12 days post egg deposition at initiation. The study authors reported that the test material was stable in dilution water for 48 hours based on a separate stability analysis, but the authors did not confirm test levels in the study. No undissolved test substance was observed in any test chamber. The study authors very little mortality where one test organism died at 72 hours in the control. One organism exhibited sublethal effects of mottled coloration and abnormal position on top of the sand substrate at 48 hours. The study authors reported a 96-hour LC50 at >1 mg a.i./L.

It is also important to note that data submitted to EFSA[10] confirms the conclusions from the preliminary analysis above that the degradates are substantially less toxic to aquatic invertebrates than the parent compound. The studies explored the acute toxicity of imidacloprid 5-hydroxy (24 hour static) and nitroso (24 hour static) degradates, as well as the chronic toxicity of the desnitro (28 day chronic), urea (28 day chronic), AMCP (28 day chronic), and desnitro olefin (28 day chronic) degradates, to *Chironomus riparius* (**Table 7**). The European data suggest that the 5-hydroxy and nitroso degradates are both nearly an order of magnitude less toxic than the parent

[10] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

compound on an acute exposure basis to *Chironomus riparius*, which is a very sensitive aquatic invertebrate to imidacloprid exposure. The rest of the degradates, however, are several orders of magnitude less toxic than the parent compound, as seen on a chronic exposure basis. One area of uncertainty related to these degradates is long-term toxicity of the 6-chloronicotinic acid to benthic invertebrates. Parent imidacloprid is expected to persist at low levels in the sediment for extended periods of time. The identified degradates in the aquatic-sediment system are the desnitro, urea, desnitro-olefin, and 6-chloronicotinic acid degradates. Chronic toxicity information on the first three degradates shows that these degradates are much less toxic than the parent compound. Acute toxicity information indicate that the 6-chloronicotinic acid is less toxic than the parent compound. However, there are no currently available chronic toxicity studies with 6-chloronicotinic acid, which is the terminal degradate of imidacloprid and is likely to lead to chronic exposure for benthic invertebrates. Nonetheless, given the comparative acute toxicity information and lower toxicity relative to the parent compound, it is likely that 6-chloronicotinic acid would also be much less toxic on a chronic basis as well.

Table 7. Toxicity values from acute and chronic studies reported by EFSA but not to the Agency. These studies have not been formally reviewed by the Agency.

Species	Test substance	Test system – duration	Parameter	NOEC (mg/L)	EC_{50}/LC_{50} (mg/L)	Type of Conc.
G. pulex	Parent	Static – 28 d	Swimming behavior	0.064		Nominal initial
Chironomus riparius	Parent	Static – 28 d	Emergence	0.00225[1]	0.00311	Nominal initial
Chironomus riparius	TEP: Confidor SL 200	Static – 28 d	Development, emergence	0.0027[1]	0.0036	Nominal initial
Chironomus riparius	Urea	Static – 28 d	Development, emergence	73.6[1]	248.7	Nominal initial
Chironomus riparius	AMCP	Static – 28 d	Development, emergence	> 105[1]	>105	Nominal initial
Chironomus riparius	Desnitro – olefin	Static – 28 d	Development, emergence	12.4[1,2]	21.3[3]	Nominal initial
Chironomus riparius	Desnitro	Static – 28 d	Development, emergence	33.61[1,2]	45.99[3]	Nominal initial
Chironomus riparius	5-hydroxy	Static – 24 h	Mortality		0.668	Nominal initial
Chironomus riparius	Nitroso	Static – 24 h	Mortality		0.283	Nominal initial

[1] EC_{15}
[2] Development rates of males
[3] Emergence ratio of pooled sexes

The toxicity of these degradates to fish is an uncertainty though because no toxicity data on the degradates have been submitted related to fish. EFED re-evaluated the degradates for this assessment using quantitative structure activity relationships provided by the EcoSAR module in EPISUITE v4.1[11] to reveal potential toxicity levels of each of these degradates to fish and those that are most relevant to the aquatic exposure assessment are listed in bold (**Table 8**). Considering the stability of the parent compound and the tidal nature of the aquatic environment,

[11] http://www.epa.gov/opptintr/exposure/pubs/episuite.htm

aquatic organisms are not likely to experience an acute peak of exposure to any of the degradates listed in **Table 8**. Instead, exposure would more likely be repeated exposures to low levels of degradates. Consequently, the chronic values estimated by EcoSAR would be most relevant. The most sensitive chronic endpoint from all of these degradates to fish was estimated to be 523 ppb from the nitrosamine degradate[12] due to the hydrazine structure; however, the nitrosamine degradate is a plant and animal metabolite and is therefore not expected to be relevant for exposure in the aquatic environment. The desnitro-olefin degradate showed the lowest estimated toxicity to fish (682 ppb), and the other degradates showed chronic endpoints higher than this degradate. Note that the chronic NOAEC and LOAEC for the parent imidacloprid from a study with rainbow trout are 1.2 and 2.5 ppm, respectively. These two values are nearly two orders of magnitude different than the 111.317 ppm value estimated by EPISUITE for parent imidacloprid, which suggests that EPISUITE is poorly estimating the potential toxicity of imidacloprid.

Table 8. Summary of EcoSAR results showing estimated toxicity values relative to fish chronic toxicity.

Degradate	Functional Group[a]	Chronic Endpt[b]
Imidacloprid parent	Aliphatic amine	111.317
Imidacloprid 5-hydroxy	Aliphatic amine	874.287
Nitrosamine (nitroso)	Hydrazine	0.523
Desnitro	**Aliphatic amine**	**4.121**
Urea	**Amide**	**1.921**
AMCP	Aliphatic Amine	4.668
Desnitro olefin	**Vinyl/allyl amine**	**0.682**
6-chloronicotinic acid	**Halopyridine acid**	**12.122**

[a] The functional group that yields the most sensitive endpoint in fish
[b] 32-day Chronic Value in ppm

In summary, the parent compound shows high levels of toxicity to free-swimming and benthic invertebrates, but relatively low toxicity to fish. EFED concludes that the degradates are not a concern to aquatic invertebrates, but rather the parent compound is the toxicologically relevant compound. In the case of fish, the toxicity of the degradates is uncertain due to the poor performance of the EcoSAR module of EPISUITE in estimating toxicity. Further consideration of the toxicity of the degradates to fish is provided in the risk characterization section of this assessment.

Terrestrial Hazard Summary

Imidacloprid appears to be highly toxic to avian species on an acute dose based level to the Japanese Quail (LD_{50} = 31 mg a.i./kg bwt) and slightly to practically non-toxic to birds on a

[12] See Appendix 3 for chemical structure. Target site potency and selectivity of neonicotinoid insecticides may be "retained when the usual neonicotinoid N-nitroimine (=NNO(2)) electronegative tip is replaced with N-nitrosoimine (=NNO) or N-(trifluoroacetyl)imine (=NCOCF(3))". See: Tomizawa M, Zhang N, Durkin KA, Olmstead MM, Casida JE. 2003. The neonicotinoid electronegative pharmacophore plays the crucial role in the high affinity and selectivity for the Drosophila nicotinic receptor: an anomaly for the nicotinoid cation--pi interaction model. Biochemistry 42(25):7819-27.

subacute level (Bobwhite quail LC_{50} = 1,536 ppm; Mallard duck LC_{50} > 4,797 ppm). However, exposure to the granular product (2.5G) on a dose basis could result in high toxicity to small birds (house sparrow LD_{50} = 41 mg/kg) and confirms the results of the study with Japanese quail that imidacloprid is highly toxic to some avian species. It also confirms that Bobwhite quail and especially the Mallard duck are relatively less sensitive to imidacloprid exposure. Consequently there is uncertainty related to the dietary toxicity of imidacloprid due to relatively insensitive species being tested in these studies. In terms of chronic toxicity, data show that imidacloprid exposure can result in egg shell thinning and a decrease in adult weight (NOAEC/LOAEC = 36/>61 ppm).

Mammalian toxicity data suggest that this compound is moderately toxic on an acute basis (LD_{50} = 424 mg/kg) to small mammals. Reproductive effects were noted at 250 ppm.

Terrestrial invertebrates are very sensitive to imidacloprid. Acute toxicity data on honeybees show that imidacloprid is very highly toxic to non-target insects (LD_{50} = 0.0039 for acute oral and LD_{50} = 0.078 ug/bee for acute contact). There are also data on the toxicity of residues on foliage for imidacloprid which shows an RT_{25} of 8 hours for the maximum application rate of 0.5 lb a.i./A (MRID 42632901). In addition, a preliminary review of the open literature suggests in general that imidacloprid has a strong potential to elicit sublethal effects. However, uncertainty remains as to how these sublethal effects translate into effects impacting survival, growth, or reproduction.

Risk Characterization

Risk to Aquatic Organisms

The risk from upper bound exposure scenarios are presented in **Tables 9**, **10**, and **11**. The scenarios reflect the two formulations that are proposed for use on oyster beds in Willapa Bay and Grays Harbor. In these two scenarios, some of the EEC's are presented based on theoretical concentrations, while others are based on measured concentrations. The differences between these two concentrations are important to keep in mind as the EEC's based on measured concentrations reflect actual residues measured *in situ*, but as noted earlier there are uncertainties associated with these measured concentrations due to limited submissions of sampling data.

Acute Risk

For acute exposure, the parent compound is the stressor of concern. Several lines of thought lead to this conclusion. First, the persistence of imidacloprid in aquatic systems as indicated by the equivalency in concentrations between peak exposure to the parent compound and the total residues shown in **Tables 2 – 5** reveals that the parent compound makes up the entire total residues for the first 24 hours of exposure. Furthermore, the flushing of the system due to the tidal nature of the mudflat habitat combined with the solubility of imidacloprid suggests that peak concentrations of parent imidacloprid may be removed from the surface water with the tide thereby leaving little residue to degrade in overlying water. In fact, **Tables 4** and **5** show the precipitous decline in residues after only 24 hours, implying that the applied imidacloprid rapidly dissipates from the system and high exposures persist for a very short amount of time.

Consequently, those organisms present on the mudflat at the time of application would experience high levels of exposure in overlying water, but organisms that migrate onto the mudflats after 24 hours would experience substantially lower levels of exposure.

Table 9. Range in exposure and acute risk to aquatic animals and risk to aquatic plants due to parent and total residues of imidacloprid in overlying water on the site of application at 0-0.1 days after treatment. RQ values in bold exceed the Agency level of concern.

Scenario/App. Rate	Depth of Water	Aquatic Animals [a]				Aquatic Plants [b]
		Type of EEC (ppb)	EEC (ppb)	Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates	Non-Vascular (non-listed/ listed)
Uses						
Flowable: 0.5 lb a.i./A	3 cm[c]	Min	244	0.001	7	0.02
		Max	872	0.005	**24**	0.09
	10 cm[c]	Min	180	0.001	5	0.02
		Max	320	0.002	9	0.03
	<10 cm[d]	Max	1400	0.009	**38**	01

[a] Toxicity values are based on studies with mysid shrimp (*Mysidopsis bahia*) for estuarine/marine invertebrates (EC_{50} = 37 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 163,000 µg a.i./L).
[b] Toxicity values are based on studies with green algae (*Scenedesmus subspicaus*) for non-vascular plants (EC_{50} > 10,000 µg a.i./L; NOAEC = 10,000 µg a.i./L). No other data are available for aquatic vascular and non-vascular plants.
[c] Theoretical concentrations based upon estimated concentrations in the water column.
[d] Maximum measured concentration from monitoring data on-bed at the site of application.

Table 10. Most conservative exposure scenarios for acute risk to aquatic animals and risk to aquatic plants due to estimated levels of parent imidacloprid in shallow tidal water with different types of sediment and mixing depth. RQ values in bold exceed the Agency level of concern.

Scenario/App. Rate	Location	Type of Sediment	Sediment Mixing Depth	Reference Water Depth	Peak EEC (ppb)	Aquatic Animals [a]		Aquatic Plants [b]
						Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates	Non-Vascular (non-listed/ listed)
Uses								
Flowable: 0.5 lb a.i./A	Shallow tidal water	Fine	3	3	600	0.004	**16**	0.06
		Fine	10	3	245	0.002	7	0.02
		Sandy	3	3	872	0.005	**24**	0.09

[a] Toxicity values are based ort studies with mysid shrimp (*Mysidopsis bahia*) for estuarine/marine invertebrates (EC_{50} = 37 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 163,000 µg a.i./L).
[b] Toxicity values are based on studies with green algae (*Scenedesmus subspicatus*) for non-vascular plants (EC_{50} > 10,000 µg a.i./L; NOAEC = 10,000 µg a.i./L). No other data have been reviewed for aquatic vascular and non-vascular plants.

As shown in **Table 9** and **Table 10**, the peak concentrations based on both theoretical and measured concentrations lead to risk below the LOC for fish. In fact, acute exposure values do not exceed the LOC for either listed or non-listed estuarine/marine fish at on-site locations and

consequently would not exceed the LOC at off-site locations where concentrations are likely to be substantially lower. Consequently, EFED does not anticipate that the use of either formulated product will negatively affect fish based on direct toxicity at the site of application in Willapa Bay and Grays Harbor where water concentrations are expected to be the greatest.

Similar to fish, EFED also does not anticipate that risk to aquatic plants will exceed the LOC either at on-site or off-site locations based on the RQ's presented in **Tables 9** and **10**. Risk to plants represents an uncertainty however, in that the only available study that has been reviewed on aquatic plants for imidacloprid relates to aquatic non-vascular plants. Therefore, the risk picture for aquatic vascular plants due to the proposed uses remains uncertain even though the current data indicate minimal risk. Additional data on the toxicity of imidacloprid to *Lemna gibba* (MRID 48648601) has been submitted but is currently in review.

In contrast to the other taxa, acute risk to invertebrates other than mollusks in Willapa Bay and Grays Harbor immediately after applications exceeds the LOC for both listed and non-listed species. Mollusks appear to be considerably less sensitive to imidacloprid than other invertebrate taxa. The extent of the risk is also important to consider. For on-site applications, the risk is well above the LOC, and EFED anticipates that non-target invertebrates, including free-swimming as well as benthic for which mysid shrimp serve as a surrogate, at the site of application will be at substantial risk for direct toxicity from imidacloprid where RQ's range from 5 up to 38. Benthic invertebrates are also considered to be at acute risk given that maximum concentrations used for RQ estimation in **Tables 9** and **10** for overlying water are similar to maximum pore-water concentrations in **Tables 2** and **3**, and the same toxicity endpoint for mysid shrimp would be used.

Considering off-site acute risk, EFED assessed the distance of 30ft off-site from the application area and in the direction of tidal outflow. Concentrations in pore-water are close to the detection limit, and therefore overlying water concentrations are expected to be negligible. However, when comparing the estimated pore-water EEC's to the mysid shrimp toxicity data, the off-site RQ for the flowable formulation is 0.05, and it is 0.02 for the granular formulation. The flowable formulation reaches the listed species LOC of 0.05, but these peak concentrations are not expected to remain for very long. These risk estimates off-site are based on actual measured concentrations from data provided by the Oyster Growers Association of Willapa Bay and Grays Harbor. Thus EFED concludes that risk to federally listed benthic invertebrates would remain above the LOC even to the extent of 30ft off-site, but not for non-listed free-swimming or benthic invertebrates. However, it should be noted that there are no benthic invertebrates that are currently listed as threatened or endangered in Willapa Bay and Grays Harbor. EFED also notes that there is uncertainty in the exposure estimates for off-site locations given the need for additional monitoring data.

Chronic Risk

In terms of chronic risk, **Table 11** reveals a trend similar to that for acute risk. The chronic EEC's do not exceed the LOC for either listed or non-listed estuarine/marine fish. The lack of exceedances relates to both parent imidacloprid and when total residues are taken into consideration. Regarding potential risk to fish from exposure to the degradates, **Table 8** shows

that most of the estimated chronic endpoints for the degradates are well above the estimated exposure concentrations. Yet these comparisons contain uncertainty. To explore this uncertainty a bit further, the conservative assumption can be made that all of the total residues at the final time point are made up of the degradate of concern. For example, the maximum 35-day on-site EEC for the parent compound in overlying water is estimated to be 21.53 ppb (

Table 6). As **Table 4** shows, the ratio of the parent to the total residues in pore water at 28 days after application indicates that the parent comprises 32% of the total residues. Consequently, in the case of desnitro olefin, 68% of the total residues could be conservatively assumed to be the desnitro olefin, which is estimated to be the most toxic of the relevant degradates, leading to a concentration of 45.75 ppb. In this case, the desnitro olefin degradate would have to be nearly two orders of magnitude more toxic than the estimated endpoint.

Considering that EPISUITE is underestimating toxicity of the parent compound by approximately two orders of magnitude, it is possible that the estimated toxicity endpoint for the desnitro olefin is also underestimated by two orders of magnitude leading to a chronic endpoint of approximately 6.82ppb. The desnitro olefin may therefore be of toxicological concern related to chronic exposure. In addition, the chronic toxicity endpoints for the urea degradate would be 19.21ppb and the desnitro (guanidine) would be 41.21ppb, so both of these degradates would also be of concern. The uncertainty therefore relates to the concentrations of the degradates in the tidal estuary and the obvious underestimation of toxicity by EPISUITE. From an exposure basis, fish would have to return to the same mudflats to receive repeated pulses of exposure. In addition, all of the total residues would have to be in the form of the relevant degradates identified above. These are conservative assumptions. In addition, to date, EFED is not aware of information on the formation rates specifically of the desnitro olefin in estuarine-marine systems so it is unclear to what extent this degradate may form. From the *in-situ* monitoring data available, it appears that overlying water concentrations on bed of the parent compound are below detection limits after one to three days post application, which is different than the modeling results and indicates that actual overlying water concentrations may be negligible. Yet pore water data using the ELISA method reveal that the desnitro, olefin, and urea degradates are forming. In summary, EFED concludes that exposure of fish to the degradates and the consequent risk may be minimal; however, there is uncertainty as to the actual concentrations of the degradates in the overlying water due to only partial submissions of monitoring data and lack of toxicity testing of these degradates on fish. In light of these uncertainties, EFED is not able to make any definitive risk conclusions regarding the potential for chronic exposure to the degradates for fish at on-site locations. Based on comparisons between on-site and off-site pore water residue levels, EFED anticipates that off-site concentrations of the degradates in overlying water will be negligible, therefore the primary uncertainty for chronic exposure to fish is relevant to on-site areas that have received a direct application.

Unlike fish, risk exceeds the chronic LOC for free-swimming and benthic invertebrates on the site of application. When considering off-site risk, the RQ's slightly exceed the LOC for benthic invertebrates. There is uncertainty in this comparison and these RQ's related to sediment toxicity, however. The sediment toxicity value is based on the mysid shrimp, and it is unclear how well the mysid toxicity relates to benthic invertebrate toxicity. No acceptable data have

been submitted that address benthic invertebrates in estuarine/marine systems. Chronic concentrations in overlying water are expected to be negligible off-site as the pore-water concentrations are themselves barely above the detection limit, though there is uncertainty due to an incomplete evaluation of residue levels in overlying water because of only partial submissions of data.

It is important to consider that the EEC's used to calculate the RQ's for the benthic invertebrates are based on total residues. Given the data currently submitted to Europe and the Agency regarding the degradates, noting the uncertainty of not having reviewed this data and the lack of chronic toxicity data on sediment invertebrates, EFED does not anticipate the degradates to be of significant concern to benthic invertebrates and therefore the concentrations of parent imidacloprid are likely the residues of concern. **Table 4** reveals instantaneous water concentrations and shows that at 28 days, the parent makes up 32% of the total residues measured. If this percentage is applied to the off-site RQ's in **Table 11**, the RQ for the flowable formulation just reaches the LOC of 1, but the RQ for the granular formulation falls below the LOC. Another important consideration is that the residues are only detected in off-site pore-water up to **14** days post application. By day 28 residues are not detectable, and consequently the exposure would not persist to 28 days. Consequently, EFED anticipates potential chronic risk for benthic invertebrates up to 30ft off-site from the flowable formulation, but not for the granular formulation, and notes that concentrations appear to drop below detection limits by 28 days post application.

Table 11. Measured pore water concentrations and chronic risk to aquatic animals and risk due to parent and total residues of imidacloprid on-site. Risk Quotient values in bold exceed the Agency level of concern.

Scenario/App. Rate	Location	Residue of Concern	Aquatic Animal RQs[a]				
			21 day/ 35 day overlying water EEC (ppb)[b]	21 day pore water EEC (ppb)[c]	Estuarine/ Marine Fish	Estuarine/ Marine Free-swimming Invertebrates	Estuarine/ Marine Benthic Invertebrates
Uses							
Flowable: 0.5 lb a.i./A	On-site	Parent	31.66/ 21.53	34.3	0.02	**53**	**57**
		Total Residues	N/C[d]	107.1	N/C	N/C	**179**
	Off-site	Total Residues	N/C	**1.6**	N/C	N/C	**3**
Granular: 0.5 lb a.i./A	On-site	Parent	N/C	9.9	N/C	N/C	17
		Total Residues	N/C	30.8	N/C	N/C	**51**
	Off-site	Total Residues	N/C	0.5	N/C	N/C	**1**

[a] Chronic toxicity values are based on studies with a free-swimming saltwater invertebrate mysid shrimp (*Mysidopsis bahia*) (NOAEC = 0.6 µg a.i./L) and rainbow trout (*Oncorhynchus mykiss*) for freshwater fish (NOAEC = 1200 µg a.i./L). For benthic invertebrates, the chronic toxicity value is also based on mysid shrimp due to a lack of data on benthic saltwater invertebrate species.

[b] EEC's in overlying water for use in calculation of fish and free-swimming invertebrate RQ's. Overlying water concentrations are based on the maximum overlying water concentration from the most conservative scenario with the flowable formulation on sandy sediments with

minimal overlying water at the time of application (Table 6).
[c] EEC's in pore water for use in calculation of benthic invertebrate RQ's.
[d] N/C = the EEC's were not calculated, but rather only the maximum 14 day.

For free-swimming invertebrates, chronic risk as identified above has some uncertainty. First, chronic exposure assumes that the same organisms migrate to the same location following multiple tide cycles. Second, the overlying water concentrations from the in-situ monitoring data show that residues are expected to rapidly dissipate and are not detectable after 24 hours post application. Third, the degradates appear to be much less toxic to aquatic invertebrates relative to the parent compound. So while low levels of residues persist in pore-water over time, the limited monitoring data suggest that these residues may not remain in overlying water. EFED raises the concern, however, that additional data have yet to be submitted that may shed more light on the concentrations in overlying water. At present, EFED therefore concludes that based upon modeling estimates, the potential chronic risk exceeds the LOC for free-swimming invertebrates on the site of application.

A number of reports have been informally submitted to the Agency that assess the biotic communities in order to shed light on the risk conclusions from this screening level assessment. These reports include data on the effects of imidacloprid to invertebrate and fish populations living on the oyster beds following applications of imidacloprid. However, the data were not formally submitted for review and are partial and/or incomplete. The studies include:

> "Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".
> [This is a preliminary report on the results of the 2011 residue and effects monitoring; a full citation was not available and the data provided were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency. This report is expected to provide further information on the concentrations of imidacloprid in the water column, pore-water, and in sediments arising from applications to oyster beds. The report is also slated to provide further validation of the precision and accuracy of an ELISA analytical technique compared to the standard HPLC technique.]
>
> Booth, S.R., K. Rassmussen, and A. Suhrbier. 2011. Impact of imidacloprid on epi-benthic and benthic invertebrates: 2011 studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp: Preliminary results from one of two study sites and three of five sample dates. This is a preliminary report on the results of the 2011 effects monitoring; a full citation was not available and the data provided were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency.

These data include evaluations of the abundance, diversity, and richness of three taxa including polychaetes, mollusks, and crustaceans on the site of application at three time points up to 28 days post application. These preliminary data from Booth et al., 2011, do not show significant differences in the comparisons between the treated plots and the control plots. However, when the data are looked at in terms of time trends and what occurs on the plots over time to 28 days post-application, the overall trends in abundance for polychaetes and crustaceans decrease, but not for the mollusks. A preliminary review suggests that diversity and species richness do not appear to be affected, but rather the main impact is to abundance. For example, at the Bay Center plot following applications of granular imidacloprid at 0.5lb/A on July 15, the overall abundances of polychaetes, mollusks, and crustaceans on the treated plot at day 28 post

application (final measurement point) were 36%, 432%, and 50%, respectively, of the day 0 levels. As a comparison, day 28 overall abundances of these taxa in the reference plots were 68%, 114%, and 141%, respectively, of the day 0 levels. These data do not identify recovery in abundance but rather simply capture time points on a decreasing trend. However, this data is from only one of two study areas, and the study report has not been formally submitted. Furthermore, no data were presented on impacts to these three taxa off-site. So while chronic effects to these two taxa appear possible for both formulations at least 28 days post application on site, EFED cannot draw any robust conclusions from the submitted information. Nonetheless, the preliminary data confirm the concerns highlighted in this risk assessment that acute and chronic exposure pose a concern for invertebrate communities on the site of application. The data also highlight the concern that increasing acreage subject to application from potential increases in ghost and mud shrimp recruitment rates can lead to increases in the spatial extent of long-term impacts on invertebrate abundances, including polychaete and crustacean taxa.

A final point to note is that the substrate to which imidacloprid is applied appears to make a difference. Sandy substrates contribute to higher concentrations of imidacloprid in overlying water according to modeled estimates. Therefore, the risk concerns for overlying water highlighted above are most pressing for sites with sandy substrates. Additional monitoring data provided by the 2011 and 2012 EUPs are important as they may potentially address this uncertainty.

Summary of Risks to Aquatic Organisms

In summary, the primary organisms of concern due to direct toxicity from both acute and chronic exposure are the benthic and free-swimming estuarine/marine invertebrates. The uses of the flowable and granular formulations present risks that exceed all LOC's at onsite locations on an acute basis for free-swimming and benthic invertebrates that inhabit the sediment. In terms of chronic exposure, the RQ's exceed the LOC at onsite locations for both flowable and granular formulations for benthic invertebrates. Free-swimming invertebrates are also at risk due to chronic exposure on the site of application. Off-site risk is only present for listed benthic invertebrates on an acute and chronic basis due to the flowable formulation. In addition, it appears that sandy substrates in the bays are more prone to higher exposures, at least in overlying water, than finer texture substrates. The submitted monitoring report, however, indicates that the overlying water contains very little imidacloprid at 21 days post application and would likely not impact free-swimming invertebrates in the overlying water following chronic exposure. These data have not been formally submitted and have not been reviewed by EFED. In contrast,, according to modeling estimates, low residues in overlying water, as well as pore water, can persist weeks after applications. Therefore, there is uncertainty in the comparison of the overlying water and pore water concentrations over time related to aquatic invertebrate toxicity. Aquatic invertebrate taxa represent the base of the food chain, and impacts on these taxa will likely cascade up the food chain, resulting in a reduction in prey and modification of PCE's related to endangered species due to fewer prey, as highlighted in the conceptual diagram in **Figure 1**. Additionally, individual effects on these organisms, including crab species, can also be expected. Recruitment of other individuals to on-site locations following removal of the shrimp may be a significant pathway of recovery for the impacted taxa. However, the submitted biotic monitoring data indicate potential decreases in abundance for crustaceans and polychaetes

at least 28 days post application without evident recovery, although these results are uncertain as well because the data are partial or incomplete and have not been formally submitted for review. Nonetheless, the submitted biotic monitoring data support the aquatic invertebrate risk conclusions contained in this assessment.

While EFED recognizes that acute mortality in the immediate application site may be very high for aquatic animals trapped in tide pools and/or living in benthic sediments, the potential for off-site effects and overall impact to Willapa Bay as a whole appears limited. This is based on estimates that roughly 10% of the total acres (79,000 total acres) of the bay are under shellfish production during any given year, the label allows only one application per year, and that during a complete tidal cycle (low tide to high tide), as much as 25.4 million ft_3 of water (up to 45% of the bay's total volume) may be exchanged. Thus, the opportunity for dilution alone is significant. Although this discussion has focused primarily on Willapa Bay, it is believed that the same potential for dissipation exists for Grays Harbor where a similar percentage of the total acreage may be treated. However, EFED also notes that the potential acreage to which imidacloprid will be applied may increase if recruitment rates of ghost and mud shrimp increase. Consequently, a number of factors suggest that any increases in the acreage treated may be accompanied by increases in the spatial extent of consequent long-term impacts to the aquatic invertebrate assemblage and potential indirect effects to taxa that depend on these invertebrate species. These factors include the persistence of imidacloprid in sediment pore water for weeks after the initial application, the sensitivity of certain marine taxa to imidacloprid, the results from the risk assessment showing acute and chronic LOC exceedances for estuarine free-swimming and benthic invertebrates, and the preliminary indication that chronic effects are possible that reduce abundance of polychaete and crustacean taxa on the site of application at least up to 28 days post application without apparent recovery. It is also important to note that these impacts are primarily on the site of application with little concern off-site. Uncertainty remains regarding the risk picture off-site due to yearly applications of imidacloprid to the same oyster beds, potential increases in the acreage to which imidacloprid will be applied, and the persistence of imidacloprid residues in the sediment pore water where the concern is that residues may remain available or increase off-site over time. Consequently there is uncertainty in the spatial extent of the residues and potential impacts off-site.

Risk to Terrestrial Organisms

Plants

Imidacloprid is to be applied as a granule or spray to intertidal oyster beds. Consequently, EFED does not anticipate movement off-site via spray drift of the granule or flowable product to be a significant pathway of exposure to terrestrial plants. Therefore, risk concerns to terrestrial plants are considered negligible for the current assessment.

Birds and Mammals

A pathway of exposure from both flowable and granular formulations to both birds and mammals is through contact with contaminated sediment or vegetation following application. At the present time, the Agency does not have a method to quantify these levels of exposure, and data are limited to quantify the contribution of such exposures to the toxic burden an organism

experiences. The Agency is actively working on a screening method to quantify exposure from direct impingement of applied foliar as well as bare ground sprays, granular applications, and from incidental contact with dislodgeable foliar pesticide residues from treated or drift-impacted vegetation. Given the application methods available for imidacloprid, this route of exposure for terrestrial wildlife is possible, but no quantification of exposure concentrations and attendant risks is possible until the completion of initial screening models.

Another way that birds and mammals can be exposed to imidacloprid from the granular formulation is that birds and mammals may feed directly on the granules that may be scattered on the surface of the mudflats. The granules, formulated as Protector 0.5G, are to be spread with a conventional pesticide applicator, helicopter, or ground based vehicle. There is no restriction as to how this granule should be applied, and so applications to low tide mudflats may be made. These applications would then result in the granules remaining on the surface until either dissolution or movement following inundation from the next tide. Consequently, birds or mammals that feed in these tidal mudflats may mistake the granules for seeds and directly consume the granules. In order to evaluate the potential hazard from this method of exposure, TREX was used to ascertain the LD_{50}'s per square foot. **Table 12** shows the results of this analysis.

Table 12. The number of LD50/ft2 present following an application of Protector 0.5G at 0.5lb a.i./A. The avian values are based on the acute oral toxicity to Japanese Quail, and the mammalian values are based on acute toxicity to the rat.

Broadcast applications Granular		
Intermediate Calculations		
mg a.i./ft2:	**5.21**	
LD50 ft-2		
	wgt class (grams)	
Avian	**20**	**11.14**
	100	**1.75**
	1000	**0.12**
Mammal	**15**	**0.37**
	35	**0.20**
	1000	**0.02**

As **Table 12** shows, small mammals and, in particular, small birds would be of primary concern for exposure to the granules. However, there are important considerations when approaching these LD_{50}/ft^2 values. First, food items within an animal's diet is important to determining the potential risk of the granular application on tidal mudflats. Smaller birds that feed on tidal mudflats, such as the shore birds, are unlikely to view granules as food items given their reliance on invertebrate or small fish as prey[13]. Larger birds, such as waterfowl, would be more likely to

[13] ftp://ftp-fc.sc.egov.usda.gov/WHMI/WEB/pdf/SHOREbirds1.pdf

consume the granules mistakenly as seeds as their diets include more vegetative food items. As **Table 12** shows though, there are substantially fewer LD_{50}'s/ft^2 for large birds.

In addition, possible avoidance behavior by birds is an important consideration given the potential for consumption of the granules. Data submitted to the EPA suggest that some birds show avoidance of imidacloprid and that imidacloprid may lead to sublethal effects that reduce feeding on contaminated food sources. A previous review (D205523; 08/22/94) summarized the data on avoidance behavior and found that some birds immediately avoided the contaminated food (house sparrow) or showed immediate consumption of the food followed by a reduction in contaminated food consumption (turtledoves). In one study submitted to the European Union[14] but not to the U.S. EPA, the avoidance of contaminated material was found in a dietary study with the Japanese quail, which is also the most sensitive species based on acute oral toxicity data. In all cases, birds appear to develop avoidance of imidacloprid contaminated food items. A similar avoidance would likely be exhibited for granules that may be used as a food source by birds in the larger weight class, which is also the less sensitive of the different size classes. Considering the use pattern and the short duration during which the granules would be available prior to inundation as well as the limited acreage to which imidacloprid would be applied as a granule, acute exposure to birds through direct consumption of the granules is of low concern and chronic exposure is negligible based on the tidal nature of the system and the dilution of imidacloprid. Consequently, EFED expects negligible risk due to consumption of granules by birds.

In a similar manner, **Table 12** shows that there is relatively less concern for large mammals than for small mammals. However, small mammals are unlikely to forage in the mudflats where oysters would be grown due to the potential for exposure and then predation. However, larger mammals may move to the mudflats to feed and forage. According to **Table 12**, there are only 0.02 LD_{50}/ft^2, which indicates that there is relatively little toxicity to large mammals per square foot given the assumption that a mammal consume the granules. Therefore, similar to birds, direct consumption of granules is of low concern as a route of exposure to mammals on tidal mudflats.

A final pathway of exposure to birds and mammals is through contamination of food items. Food items may include plant material as applications may be made where eelgrass is present. In addition, food items would also include invertebrates that are directly sprayed during low tide and fish and invertebrates that are contaminated through uptake following exposure in the water column or through contact with sediments in between low tides. For fish and invertebrates that are exposed to imidacloprid in the water column or through contact with the sediment, body burden concentrations are expected to be negligible with minimal accumulation within the food chain due to the low K_{ow} of imidacloprid. For chemicals with Log $K_{ow} < 4$, exposure from food becomes insignificant because uptake and depuration across the gills controls the residue in the organism. Imidacloprid is highly hydrophilic with a log Kow of 0.57 and therefore would not accumulate appreciably in the stored fats of invertebrates or fish. Consequently, these prey items would likely have little contamination for birds and mammals feeding on them. **Table 13**

[14] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005. Table 2.6-6

presents the results of the exposure modeling and consequent risk conclusions. As expected, the acute risk is all well below the various levels of concern.

Chronic risk via this pathway of exposure is an uncertainty due to the tidal nature of the ecosystem. As the data to date show, most of the residues in the water column and sediment pore water are removed from the system following the first tidal inundation. Therefore, low concentrations of persistent residues in the sediment combined with extremely limited potential for bioaccumulation leads to EFED's conclusion that chronic risk to birds and mammals is negligible from feeding on organisms exposed to concentrations of imidacloprid in the water column and sediments. However, there is uncertainty as not all of the data for imidacloprid applications to oyster beds have been submitted yet.

EFED also used KABAM to evaluate chronic exposure, and as expected **Table 13** shows little concern for birds and mammals that are chronically exposed to imidacloprid from eating aquatic food items contaminated by bioaccumulation.

Table 13. Calculation of Risk Quotient values for mammals and birds consuming fish contaminated by Imidacloprid using KABAM. Across the range of potential mammal and bird body weights, none of the RQ's exceed any level of concern. Modeling with KABAM used the default input values, which represents a conservative scenario of exposure and potential accumulation within the food chain. The imidacloprid input parameters for water column EEC and pore water EEC were 38.9 and 97 ppb, respectively, which were residue levels at one day after application based on a KABAM calculated 2 days to steady state.

Wildlife Species[a]	Acute RQ		Chronic RQ	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	0.000	N/A	0.001	0.000
rice rat/star-nosed mole	0.000	N/A	0.001	0.000
small mink	0.000	N/A	0.001	0.000
large mink	0.000	N/A	0.001	0.000
small river otter	0.000	N/A	0.002	0.000
large river otter	0.000	N/A	0.002	0.000
Avian				
sandpipers	0.002	0.000	N/A	0.001
cranes	0.000	0.000	N/A	0.001
rails	0.001	0.000	N/A	0.001

herons	0.000	0.000	N/A	0.001
small osprey	0.000	0.000	N/A	0.001
white pelican	0.000	0.000	N/A	0.001
[a] Wildlife species used in the modeling are default species and reflect a range of body sizes and food consumption patterns to illustrate the lack of concern due to consumption of contaminated aquatic prey species.				

The use of the flowable formulation as a spray may also result in surface contamination of plants and invertebrates remaining on the mudflats during applications to exposed mudflats. Some birds may eat eelgrass as a component of their diet. In addition, birds and mammals are likely to consume invertebrates as they forage in the mudflats. Fish would not be a food source to consider in this scenario as any fish would have moved out of the tidal mudflat with the retreating tide. And considerations with fish are covered by the previous scenario that EFED evaluated using KABAM. As a conservative estimation of risk to birds and mammals feeding on these food sources, TREX was used with the tallgrass scenario (eelgrass may grow up to 1.2m in length[15]) to reflect consumption of plant material by birds and mammals, and the arthropod scenario reflected consumption of invertebrates that may be exposed to direct sprays of Protector 2F. The results are presented in **Table 14**. Again, due to the tidal nature of the system, chronic risk is expected to be minimal. Given the solubility and low K_{ow} of imidacloprid, the residues on any exposed invertebrates are likely to move into solution when the tide returns. Consequently, the chronic exposure via this pathway would be negligible following the first tidal inundation after the spray event and therefore not pose any chronic risk concerns.

Table 14. Acute RQ's based on the tallgrass and arthropod scenarios in TREX for birds and mammals consuming prey items contaminated by direct exposure to sprays during low tide.

Scenario	Avian RQ's			Mammalian RQ's		
	20g	100g	1000g	15g	35g	1000g
Tallgrass	**2.68**	**1.2**	**0.38**	0.06	0.05	0.03
Arthropod	**2.29**	**1.03**	**0.33**	0.05	0.04	0.02

As **Table 14** reveals, there are no mammalian acute risk concerns, but risk exceeds the acute level of concern for birds. The RQ exceeds the LOC for federally listed large birds such as waterfowl that feed on either eelgrass or aquatic invertebrates. In addition, both listed and non-listed medium and small birds, such as shorebirds, would also be of concern based on the exceedance of the listed and non-listed species LOC's. It is important to remember that these exceedances correspond to acute toxicity related to applications of Protector 2F made specifically at low tide to exposed mudflats with minimal or no standing water.

It is also important to note that there is uncertainty in these exposures in TREX. TREX estimates are based on the Kenaga nomogram using residue data on terrestrial plants and invertebrates. It is unknown how well these exposure values relate to applications made on tidal mudflats and the plants and invertebrates that occupy these habitats. Furthermore, the invertebrates on the tidal mudflats would likely burrow during periods of low tide to escape predation, and so they are

[15] http://plants.usda.gov/java/profile?symbol=ZOMA

unlikely to be exposed when there is no water covering the mudflat as a spray application is made. While unlikely, it is still possible that the invertebrates may be exposed to direct spray applications. Plants would be present, and so while consumption of invertebrates exposed to direct spray applications of Protector 2F is unlikely, consumption of contaminated plants is more likely and presents the primary concern related to this application. Consequently, there is little concern for mammals at all, and little concern for birds when Protector 2F is applied with standing water. However, use of Protector 2F during the peak of low tide when a mudflat is completely exposed poses a risk concern to listed and non-listed birds that consume invertebrates and most especially plant material.

Invertebrates

Terrestrial invertebrates are unlikely to be in the vicinity of the tidal mudflats during applications while water is present, therefore exposure, especially to bees, would be negligible. However, invertebrates other than bees may move into the tidal mudflats at low tide to feed. These invertebrates would also be susceptible to spray applications made to mudflats via potential contact exposure. The granular use would require standing water for dissolution to spatially disperse the active ingredient over the mudflat. With this in mind, EFED does not anticipate substantial contact exposure to terrestrial invertebrates from the use of Protector 0.5G at any point in the tidal cycle. However, the Protector 2F formulation warrants further evaluation based on the potential for exposure. Assuming an application of 2F at 0.5 lb a.i./A, terrestrial invertebrates could be exposed to direct sprays or to contact with contaminated sediments. EFED used the TREX arthropod scenario to evaluate an application of imidacloprid spray at 0.5 lb a.i./A to arrive at a contact EEC for terrestrial invertebrates on mudflats exposed to direct sprays. The EEC provided by TREX is 47 mg/kg bwt. For comparison, the honey bee contact LD_{50} is 78 ng/bee. A honey bee typically weighs approximately 0.128 g[16]. Consequently, 47 mg/kg bwt multiplied by 0.000128 kg (bee bodyweight converted to kilograms) equates to 6 µg a.i./bee, which is nearly two orders of magnitude greater than the LD_{50} and exceeds the level of concern of 0.4 for bees[17].

Another potential pathway of exposure involves direct contact with contaminated sediments when terrestrial invertebrates move to the mudflats at low tide when sediments are exposed. Imidacloprid applications would involve an application rate of 0.5 lb a.i./A. This rate was evaluated in a study that examined the toxicity of residues on foliage using the honey bee (MRID 42632901). The study found that imidacloprid has a residual toxicity of 8 hrs on foliage contaminated by direct spray, indicating that mortality will exceed 25% of the test organisms within a timeframe less than 8 hrs after application. Consequently, the surface of the mudflat sediment could remain very toxic to terrestrial invertebrates that move to the mudflats until the tide returns following applications of Protector 2F to exposed mudflat surfaces.

Similar to the assessment with birds and mammals, there is uncertainty in the use of TREX to evaluate risk concerns for terrestrial invertebrates on mudflats. The exposure values in TREX were derived from measurements on terrestrial arthropods in terrestrial environments. It is unclear how well these estimates in TREX correspond to actual residue levels on mudflat

[16] Mayer, D. & C. Johansen. 1990. *Pollinator Protection: A Bee & Pesticide Handbook.* Wicwas Press. Cheshire, Conn. p. 161

[17] US EPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees.

invertebrates following direct exposure to spray applications. In addition, the study on the toxicity of residues on foliage evaluated applications in a terrestrial environment to dry foliage. It is uncertain how well the residues on foliage in a terrestrial environment correspond to residues on the surface of a mudflat.

Without additional data specific to applications on mudflats to address these sources of uncertainty, current evaluations of exposure and the hazard described by the RT_{25} indicate concerns for terrestrial invertebrates other than bees due to applications of Protector 2F only to exposed mudflat surfaces. These invertebrates also represent the base of the food chain and are important to ecosystem functioning. However, it is also important to note that imidacloprid applications are only permitted according to the proposed label once per year at 0.5 lb a.i./A. Therefore the risk would only be present for a short duration prior to the next inundation, so the period of concern would last only a couple of hours.

Summary of Risks to Terrestrial Organisms

In terms of terrestrial taxa, risk is only present for the flowable formulation but not the granular formulation. For the granular formulation (Protector 0.5G), the avoidance behavior exhibited by birds, the unlikely consumption of granules by larger mammals feeding in the mudflats, and the requirement that the granules dissolve on the mudflats to lead to surface residues leads EFED to conclude that the granular use on exposed or inundated mudflats will not pose a risk concern for terrestrial taxa. For the flowable formulation (Protector 2F), EFED found no risk to mammals, and the risk to birds appears to be for applications of Protector 2F at low tide to exposed mudflat surfaces. Similarly, the concern for terrestrial invertebrates other than bees also relates to the same application of Protector 2F to exposed mudflat surfaces. In summary, only applications of Protector 2F to exposed mudflat surfaces with or without vegetation (*e.g.*, eelgrass) pose a risk concern to terrestrial taxa, but this risk persists for a relatively short amount of time as inundation is expected to rapidly dilute the residues of imidacloprid. Based on preliminary data, this risk concern could be addressed by limiting applications of Protector 2F to periods when there is standing water over the mudflats. The data do not definitively answer the question of how much water should be on the bed though because measurements on eelgrass were not taken at various times immediately after application, but rather at 24 hours after application at the earliest time. The additional monitoring data that have yet to be submitted to the Agency may address this question.

Uncertainties and Additional Data Needs

Uncertainties

There are a number of uncertainties related to the proposed use of imidacloprid on oyster beds in Willapa Bay and Grays Harbor. First, there are uncertainties related to data submitted to EFSA but not to the Agency. These data include a variety of studies on the toxicity of parent imidacloprid and various degradates to aquatic invertebrates and an avian dietary toxicity study with the Japanese quail. EFED has reviewed the summaries provided in the EFSA report on

imidacloprid[18]. These summaries provide an overview of the findings by the European Agency; however, EFED has not been able to formally review the data from these studies and therefore the use of the results of these studies in the risk assessment contains some uncertainty.

A number of studies have been submitted to the Agency and are currently in review (MRIDs 43946601, 43946602, 43946603, 43946604, 44558901). These studies include acute toxicity data on the desnitro, urea, and 6-chloronicotinic acid degradates to *Hyallela azteca* and/or *Chironomus tentans.* EFED has conducted a preliminary review of these studies, and acceptability of these data do not appear to change the risk conclusions contained in the risk assessment. If the final reviews of these data provide additional information that alters the conclusions in the assessment, then EFED will revise its risk assessment as appropriate.

For aquatic taxa, there are currently no endpoints available for sediment toxicity to estuarine/marine benthic species. In the absence of data specifically for benthic estuarine/marine species, the data from mysid shrimp will be used as a surrogate. As shown by the data, mysid shrimp appear to be the most sensitive species to imidacloprid. However, there is uncertainty as to whether mysid shrimp would be more or less toxic than other benthic taxa. Using mysid shrimp as a surrogate may overestimate risk to benthic species, but the use of mysid data is likely a conservative approach to evaluating risk to both benthic and free-swimming organisms.

The environmental exposure potential to desnitro olefin imidacloprid is uncertain. Although desnitro olefin imidacloprid has not been identified in field studies reviewed by the Agency to date, it has been reported to have been found in some other field studies[19]. Imidacloprid degradation in many of the submitted laboratory and field environmental fate studies was slow enough such that the full extent of formation of degradation products was not determined and there remain uncertainties regarding the long-term potential for exposure to imidacloprid degradates.

Finally, as highlighted in the risk characterization sections, there is some uncertainty as to the modeling approaches using TREX to evaluate risk to terrestrial organisms. TREX was not validated using data from tidal estuarine systems, so there is uncertainty as to how well TREX residue estimates reflect those that may be on aquatic vegetation or invertebrates within the tidal system as found in Willapa Bay and Grays Harbor.

Additional Data Needs

There are a number of uncertainties that also translate into data needs related to the proposed use of imidacloprid on oyster beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and

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[18]Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

[19] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

[19] For a reference to these data see: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2002_eva/IMIDA_EVjjb.pdf and http://ethesis.inp-toulouse.fr/archive/00000579/01/al_sayeda.pdf. Additional discussion is provided in Appendix A.

overlying water. Furthermore, while preliminary data have been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro, and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

Appendix A. Environmental Fate and Transport

a. Degradation

Hydrolysis of Imidacloprid (161-1)–Imidacloprid was stable to hydrolysis in pH 5 and 7 buffer solutions, and slowly degraded at pH 9 with an extrapolated half-life of 355 days (MRID 42055337; EFGWB[20] review nos. 92-0210, 92-0196). No degradation products accumulated significantly during the course of the study.

Photolysis in water (161-2)– The only environmental fate study in which extensive degradation occurred within a period of hours or a few days was the aqueous photolysis study (MRID 42256376; EFGWB reviews no.92-0847, 92-1039, and 92-1042). The possibility of rapid photolysis has some obvious implications for surface water exposure, but should not be assumed to universally occur in surface waters because there is not supporting evidence from surface water monitoring studies, the photolytic rate can be substantially different from distilled water in natural waters, and the amount of pesticide actually exposed to sunlight can be quite low in many surface waters.

Imidacloprid degraded with an "environmental" half-life of 4.2 hours (0.2 days) in pH 7 buffer solutions maintained at 24EC[21]. The 50% and 75% disappearance times were approximately 1 and 2 hours, respectively.

Residue analysis. Thin-layer chromatography (TLC) in multiple solvent systems and radiometric detection (exposure of TLC plates to X-ray film) was used to confirm the identity of imidacloprid and two degradation products. In addition, residues were also determined with reverse phase high-performance liquid chromatography (HPLC). A linear analyzer was used to quantify residues eluted on TLC plates. Imidacloprid guanidine / desnitro was the most prominent degradate, accumulating to 17% of the applied imidacloprid at the last sampling interval 2 hours after treatment. The only other degradation product that was identified was imidacloprid urea, which constituted 10% of the applied material 2 hours posttreatment. No effort was made to carry the experiment on to follow the degradation of imidacloprid more completely, and other degradation products were not identified. Two other separated, but unidentified photodegradation products reach maximum levels of 13% and 8% of the applied imidacloprid when the experiment was terminated after 2 hours of irradiation.

The initial concentration of imidacloprid was 5.4 mg/l (5400 ppb) in sterile, buffered solution. The study was conducted with a Xenon lamp rather than natural sunlight (the study summary mentions that "under natural sunlight 60% of the compound were [sic] degraded after 4 hours", but a detailed description of the natural sunlight experiment was not provided). The light intensity of the lamp was 8.9 to 9.5 uW/cm^2 compared to 4.1 to 5.3 uW/cm^2 for "sunlight intensity on bright days" at the Yuki Institute in Japan, where the experiment was apparently conducted. Imidacloprid was shown to be more stable in sterile solution kept in the dark, but the

[20]EFGWB = Environmental Fate and Ground Water Branch, later disbanded and blended into the Office of Pesticide Program's reorganized Environmental Fate and Effects Division.

[21]A first-order degradation half-life of 57 minutes was calculated from the study, then assumptions were made to recalculate what the half-life should have been under normal intensity sunlight.

last sample was taken only after two hours.
This study failed to identify most of the residues by two hours after application, and also failed to demonstrate the long-term stability of imidacloprid in the dark control. Although the stability of imidacloprid at pH 7 in solution has been demonstrated in a separate hydrolysis study, this should have been confirmed in the exact same solution that was used for the photolysis study. A further limitation was that the long-term stability of imidacloprid degradation products to photolysis was not evaluated.

The primary degradation products resulting from aqueous photolysis reported in the literature by Moza et al. (1998[22]) are as follows:
- imidacloprid urea
- 6-chloronicotinic aldehyde
- 6-chloro-N-methylnicotinacidamide
- 6-chloro-3-pyridyl-methylethylenediamine

Photolysis on soil (161-3)– Imidacloprid degraded with a registrant-calculated second-order half-life of 39 days (calculated environmental half-life of 171 days). Two experiments were run, one for 5 and the other for 15 days. At the end of the 15 days, imidacloprid parent accounted for 81.6% of the applied radioactivity; consequently an accurate estimate of the degradation rate under the conditions of this test is not possible.

Aerobic soil metabolism (162-1)–Imidacloprid degraded in a Kansas sandy loam soil (series name or classification unknown; MRID 421073501) with a half life well over 1 year (the duration of the study), extrapolation of the data with assumption of continued decay at a first-order rate results in a calculated half-life of 660 days (Table E-1). In contrast, in three European soils (MRID 452393), the first-order half-lives were calculated to be 248, 341, and 188 days[23]. The mean first-order half-life was 359 days (90% upper bound confidence value of 520 days); however there appeared to be greater persistence during the latter part of these studies than predicted by a simple first-order model. These studies were conducted at 20 C (except 22 C for the Kansas soil), persistence might have been lower at 25 C, the temperature of most laboratory soil metabolism studies.

Table A-1. Summary of aerobic soil metabolism studies for imidacloprid.

Soil	% O.C.	pH in water/ 0.01 M CaCl2	% Remaining at end of study	Extrapolated half-life, days
BBA 2.2 lehmiger loamy sand (meadow soil from Hanhofen, Vorderpfalz, West Germany (MRID 452393-01; Miles #100140)	2.2	6.3/ 5.5	63.3 (100 days)	188
Hoefchen silt loam (MRID 452393-02; Miles #100141)	1.2	ND/ 5.3	66.8 (100 days)	248

[22] Moza, P.N., K. Hustert, E. Feicht, and A. Kettrup. 1998. Photolysis of imidacloprid in aqueous solution. Chemosphere. 36(3): 497–502.
[23] Studies with the BBA 2.2, Hofchen, and Monheim soils were conducted at 20 C with the soil water content kept at 40% of "water capacity". The Kansas soil study was conducted at 20 C and 75% of 1/3 bar moisture level, the 1/3 bar water content was 14.7%.

Monheim 1 sandy loam (MRID 452393-03?; Miles #101955)	1.3	?	? (100 days)	341
Kansas sandy loam (MRID 42073501, Miles #101241)	1.4	6.5/ 4.8	61.6 (366 days)	660

Under aerobic conditions no specific compound has been identified as accumulating to 10% or more of the applied in soil or water. The lack of identification of major degradates was a factor of both the limited transformation of parent compound over the duration of these studies and the failure to identify the nature of much of the residues. Anhalt et al. (2007) have reported that imidacloprid desnitro/guanidine and imidacloprid urea were products of degradation by soil microbes[24]. In studies conducted by the registrant to support registrations in Europe all degradates looked for, including the urea and desnitro / guanidine metabolites were always detected at less than 10% of the applied imidacloprid[25] (these data have not been reviewed by EPA).

Anaerobic soil metabolism (162-2)-- No anaerobic soil metabolism study has been conducted; however, an anaerobic aquatic soil metabolism study was conducted in lieu of this study.

Anaerobic aquatic soil metabolism (162-2)-- Imidacloprid degradation was evaluated in a water / sediment mixture (obtained from a pond in Stilwell, Kansas) (MRID 42256378).Characteristics of the sediment were: silt loam textural class (14% sand, 58% silt, 28% clay), 3.2% organic matter, pH 6.9. The pond water was not characterized. The study was conducted with 500 ml pond water and 100 g of sediment in flasks under unspecified conditions; imidacloprid was added to the overall system at a concentration of 0.56 ppm (presumably part per million by weight). The incubation flasks were purged with nitrogen and the maintenance of anaerobic conditions was documented with periodic measurement of redox potential, pH, and oxygen concentration. Imidacloprid degraded with a first order anaerobic half-life of 27 days over the 358-day post-application incubation period. Under the anaerobic conditions of this study, imidacloprid underwent a nitro-reduction reaction to the degradate imidacloprid guanidine / desnitro, a compound which accumulated to 66% of applied 249 days after application of parent imidacloprid. Imidacloprid guanidine / desnitro appears to be extremely persistent under anaerobic conditions; residues of this degradate still represented 64% (50% in the sediment and 14% in the water) of the applied imidacloprid at the last sampling date of 358 days posttreatment. Virtually no mineralization of imidacloprid occurred, evolved carbon dioxide represented less than 0.2% of the applied imidacloprid.

b. Mobility

Mobility/Adsorption/Desorption (163-1)--Based on two sets of batch equilibrium studies

[24] Anhalt, J.C., T.B. Moorman, and W.C. Koskinen. 2007. Biodegradation of imidacloprid by an isolated soil microorganism. Journal of Environmental Science and Health Part 8; 42:509-514.

[25] See: Anderson, C. and Fritz, R. 1990a. Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions. Bayer AG, Report No. PF3322. Date: date: 1990-12-07. Amended 1992-10-01. (not submitted to EPA).

Anderson, C. and Fritz, R. 1990b. Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions. Bayer AG, Report No. PF3434, Date: 1990-01-19. Amended: 1992-10-01. (not submitted to EPA.

(MRID 420553-38 - American soils; and M in a total of eight soils (four American and four German), parent imidacloprid is moderately mobile with Freundlich adsorption coefficients ranging between 0.96 and 4.76. Soil organic carbon partition coefficients (Koc) values did not vary greatly, the range for eight soils was 132 to 256 ml/g (161 to 239 for the four American soils) with an average Koc of 178. Results for the American and German soil studies are given in Tables E-2 and E-3, respectively. Several articles reflecting further research on imidacloprid sorption in soil have since been published in the open literature, which provide insight into topics such as the increased sorption observed with time and also with lower initial concentrations of imidacloprid in soil water. Sorption coefficients measured in published studies are generally in the same range as the registrant-submitted studies, at least over the short-term (Oi, 1999, Cox et al. 1998).

Table A-2. Imidacloprid parent adsorption coefficients in American soils (MRID 425208-01).

Soil type	K_{ads}	1/N	%OC	Koc
sand	0.96	0.78	0.4	239.0
loamy sand	1.02	0.88	0.6	170.0
silt loam	4.18	0.78	2.6	160.8
loam	3.45	0.76	2.0	172.5
silt loam w/Na azide*	4.76	0.73	2.6	183.1

*Same soil as the silt loam, amended.

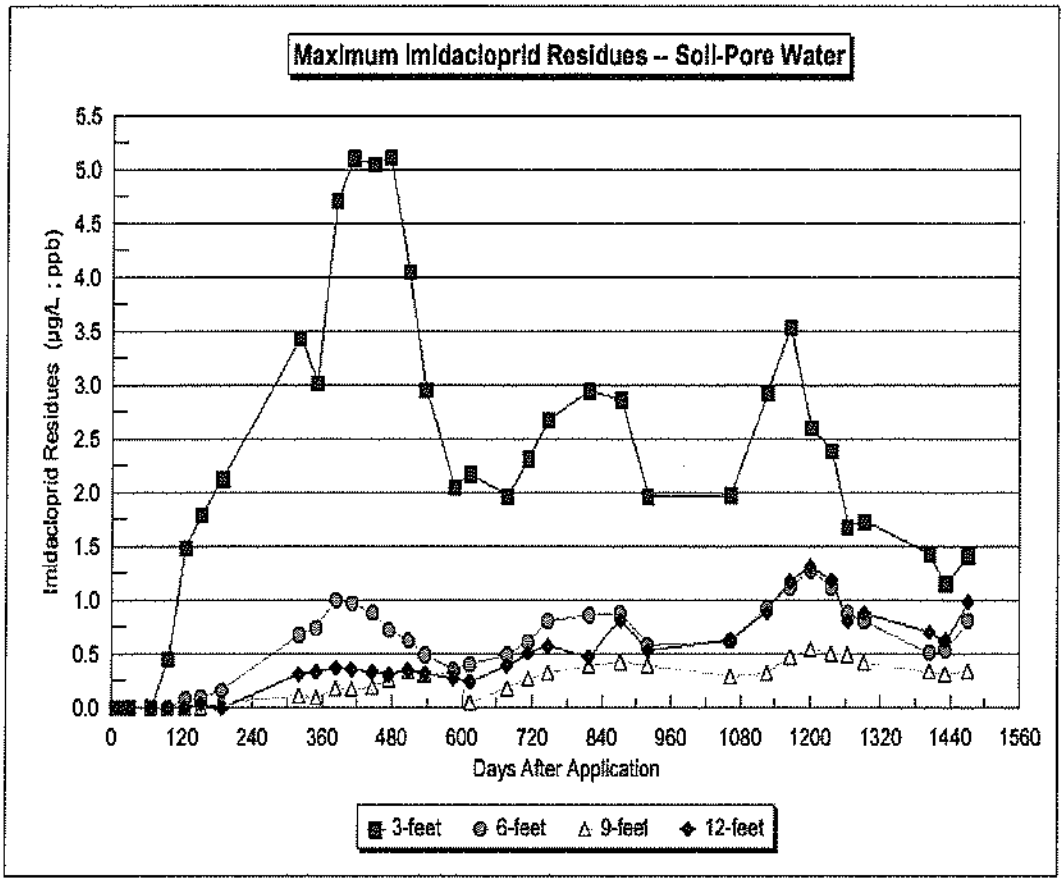


Figure A-1. Imidacloprid Small-Scale Prospective Ground-Water Monitoring Study in Michigan: results through the first 1500 days: Maximum residues found in soil pore-water at 3, 6, 9, and 12-foot depths.

Table A-3. Imidacloprid parent adsorption coefficients in German soils (MRID 420553-38).

Soil type	Kads	1/N	%OC	Koc
sandy loam	3.59	0.74	1.4	256.4
Hofchen silt	2.38	0.83	1.8	132.2
low humus sandy	1.17	0.78	0.8	156.0
Ranschbach silty clay	1.36	0.85	0.6	212.5

In addition to the above-mentioned studies, an aged soil column leaching study with imidacloprid parent (MRID 420553-39) and an adsorption / desorption study with imidacloprid guanidine / desnitro (MRID 425208-02) have been completed. In the imidacloprid guanidine / desnitro study the same four American soils were studied as with the parent compound (compare Table E-4 with Table E-2). The degradate was more strongly adsorbed than parent imidacloprid in all four of the test soils.

Table A-4. Imidacloprid guanidine / desnitro adsorption coefficients in American soils (MRID 425208-02).

Soil type	K_{ads}	1/N	%OC	Koc
sand	0.76	1.22	0.23	327.0
loamy sand	2.91	1.09	0.35	833.0
silt loam	14.20	1.02	1.51	942.0
loam	10.15	0.82	1.16	866.0

Prospective ground-water studies have been conducted at two locations and in both cases the predominant compound detected in soil, soil-pore water throughout the vadose zone, and in ground-water (when detectable) was parent imidacloprid. Of the three degradates analyzed for (imidacloprid guanidine / desnitro, olefin, and urea derivatives) only imidacloprid urea leached at concentrations that were frequently detectable (minimum detection limit of 0.02 ug/L).

There is a possibility that exposure to these degradates could be significant. Therefore, it is important that either specific analytical methods for the degradates or some sort of total residue method for residues in water and soil samples should be developed and made publicly available (specific methods would be required for any degradate identified as being of toxicological concern).

c. Accumulation

Accumulation in Laboratory Fish (165-4) This data requirement has been waived. Octanol/water partitioning (Kow) data provided by the registrant implies a low potential to bioaccumulate (Kow for imidacloprid = 3.7 @21 C).

d. Field Dissipation

Terrestrial field dissipation (164-1). Terrestrial field dissipation studies have been submitted from Georgia (loamy sand, bare ground), Minnesota (sandy loam, planted to corn), California (sandy loam, planted to tomatoes), Minnesota (loam, turf plot), and a Georgia loamy sand (turf plot) (Table E-5). The dissipation half-lives (based on analyses of 0-6 inch soil cores only) ranged from 107 days to much greater than 1 year (no significant dissipation over the one year of the study at three of the sites). In each of these studies a single or broadcast application at 0.5 lb a.i./A was made.

Table A-5. Dissipation of imidacloprid in five field studies (a single application at 0.5 lb a.i./ A was made in each study).

Study Identification	Crop	Concentration at time Zero, ug/g, or maximum concentration	Concentration after 1 year, ug/g	Calculated Half-life, days
Tifton, Georgia loamy sand	bare-ground	0.11	0.05	>365
Hollandale, Minnesota sandy	field corn	0.095	0.073	>> 365

loam				
Fresno, California sandy loam	tomatoes	0.15	0.013	146
Tifton, Georgia loamy sand (0-3 in. soil samples)	Bermuda grass turf	0.17 (28 & 63 D.A.T.)[26]	0.12 (126 D.A.T.)	107 (based on composite analyses of turf and soil)
Waseca, Minnesota loam (0-3 in. soil samples)	bluegrass turf	0.05 (60 D.A.T.	0.038 (120 D.A.T.)	>120 (based on composite analyses of turf and soil)

In each of these studies the registrant failed to confirm the application rate [see earlier EFGWB, EFED review dated approximately February 1993: "'NTN 33893' (insecticide) - New Chemical terrestrial non-food, turf, ornamentals"] and did not evaluate the formation and decline of any degradation products.

Field dissipation studies have been cited in reports by international regulatory agencies but not submitted to EPA and could potentially contain useful information on imidacloprid degradation. For example, it has been noted[27] that the following studies contain field residue data for imidacloprid desnitro olefin:

Philpot, J.D. and Yen, P.Y. 1998. Terrestrial field dissipation of imidacloprid on turf in Ontario, Canada, 1994. Bayer Corporation, Stilwell, KS, USA. Bayer AG, Report No. BR107817. Date: 1998-01-15. Unpublished.

Formella, T.M. and Cink, J.H. 1997. Imidacloprid (NTN 33893) turf dissipation in North Carolina, 1992. Bayer Corporation, Kansas City, MO, USA. Bayer AG, Report No. BR107384. Date: 1997-04-18. Unpublished.

e. Special Field Studies

Small-Scale Prospective Ground-Water Monitoring Studies (164-1).

The registrant has conducted two small-scale Prospective Ground Water Monitoring studies: one each in Montcalm County, Michigan and Monterey County, California. In both studies, the registrant monitored for imidacloprid parent, imidacloprid guanidine / desnitro, imidacloprid olefin, and imidacloprid urea in the vadose zone and in shallow ground water.

In the California study (located near Salinas, Monterey County) imidacloprid was applied at 0.45 lb a.i./A within the planting furrow (broccoli crop) in July 1996. At this site, more leaching of imidacloprid residues was found to occur in the "control" plot than in the treated area. The registrant believes the imidacloprid found in control plot samples is from four foliar applications of imidacloprid in 1995 and 1996. Although it appears that sufficient irrigation water was applied at this site to facilitate some ground-water recharge, interpretation of this study is complicated by the relative insensitivity of the analytical method for the conservative tracer

[26] D.A.T. = days after imidacloprid treatment.

[27] See: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2002_eva/IMIDA_EVjjb.pdf and http://ethesis.inp-toulouse.fr/archive/00000579/01/al_sayeda.pdf

(bromide) to be used to confirm this. In fact, there were only a handful of detections of bromide in the first 3+ years of sampling of ground water, providing no definitive evidence that sufficient water has been applied at the site for any pesticide residues of any kind to reach ground water (because little or no infiltration of water had occurred). Our conclusion therefore is, that even though there were only a few detections of imidacloprid in ground water (the highest at 0.09, 0.10 and 0.14 ppb) and the method has a claimed ability to quantitative imidacloprid at 0.01 ppb in water samples (although apparently only detections above 0.05 ppb were reported), there still could be substantial potential for imidacloprid to leach to ground water following application to irrigated vegetable or fruit crops in California (if sufficient water is added and time allowed for the aquifer to be recharged with water from the surface posttreatment). Additionally, we note that all three of the imidacloprid degradates were detected leaching through the vadose zone and there were also a few detections of imidacloprid urea in ground water at the California study site.

In the Michigan study (located near Vestaburg, Montcalm County) imidacloprid was applied at 0.34 lb a.i./A by an unspecified method (potato crop) May 31, 1996. Imidacloprid was found to be leaching at a variable rate and concentration in all six of the lysimeter clusters with residues occasionally exceeding 1 ppb at 12 feet, the lowest depth sampled (Figure 2). In the Michigan study (planted to potatoes), imidacloprid was found to be leaching at a variable rate and concentration. Detectable residues of imidacloprid occurred in all six, and in four out of six on-site lysimeters at the three and six foot depths, respectively, by 319 days after treatment (DAT 319), at concentrations up to 3.35 ppb.

Residues in ground water at the Michigan site were up to 0.24 ppb (Figure 3). Complete breakthrough into ground water was not clearly been observed; consequently it is possible that higher concentrations of imidacloprid in ground water could be observed under use conditions which promote more ground-water recharge and/or when imidacloprid is used in multiple growing seasons at the same site. Imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period (there were a very few detections before application that may have been due to previous uses nearby or sample contamination). The 0.24 ppb level might increase slightly over time if imidacloprid continued to leach into groundwater (and be applied in at least some of the subsequent growing seasons); however, the level probably would not increase dramatically given that the maximum levels seen at the three and twelve foot soil depths were 1.63 ppb and 1.31 ppb, respectively.

Data from the California site is less useful due to the fact that there appears to have been very little ground-water recharge occurring during the course of the study as evidenced by the almost complete lack of detection of the bromide tracer (applied concurrently with imidacloprid) in ground water (bromide residues in ground water never consistently and reliably exceeded the measured background levels). The maximum combined residue of imidacloprid parent and degradates found in the suction lysimeters was 0.62 ppb at 633 days post application. The maximum combined imidacloprid residue in the ground water at the California site was 0.14 ppb found 149 days post application. EPA concluded that low (sub-ppb) level contamination of potable ground water might occur in this region following application to irrigated vegetable or fruit crops.

f. Other (non-registrant) Ground-Water Monitoring

EPA has received several reports summarizing monitoring of ground water that is vulnerable to contamination in New York state (primarily Long Island). Much of this monitoring was targeted to areas with known histories of imidacloprid use and previously documented ground-water contamination issues. Suffolk County Department of Health Services reports that there were 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 samples (Electronic mail communication from Sy Robbins Suffolk County Department of Health Services, Bureau of Groundwater Resources), 1/16/2004 to Michael R. Barrett, (US EPA, Office of Pesticide Programs Environmental Fate & Effects Division).

More recently, imidacloprid has been found in domestic drinking water wells in New York state:

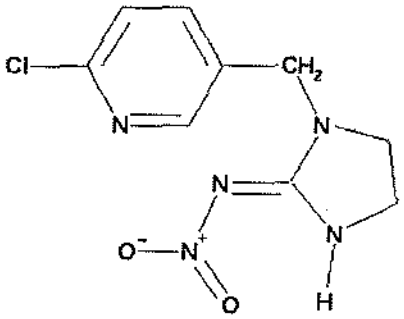
> "To date, imidacloprid has been detected at concentrations (0.2 to 7 ppb) in 12 monitoring wells and 16 down gradient private homeowner wells. Imidacloprid has also been recently detected at 0.24 ppb in two Suffolk County community water supply wells (85 feet and 90 feet deep)." (Imidacloprid NYS DEC Letter - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04)

EFED received background information on three high detections in drinking water that might indicate unusual conditions associated with each detection. The first of these wells is a private well in Mattituck, Long Island in which imidacloprid was found at a level of 6.69 ppb. An investigation by the New York authorities, concluded that these high levels were due to misuse of the pesticide in a greenhouse adjacent to the well where imidacloprid contaminated water was drained onto the ground in the immediate vicinity of the well. The second well was one of five shallow monitoring wells installed directly down gradient from imidacloprid use sites for the purpose of monitoring pesticide levels. One of those wells, "Jamesport B-2", showed levels of imidacloprid as high as 2.06 ppb. It was discovered, however, that this well was in all likelihood contaminated as a result of a manmade sump nearby that was constructed to alleviate ponding in the field and directly connected surface water to ground water.

Imidacloprid has been detected in shallow ground water wells directly downgradient from a site investigating use of tree injection treatments of imidacloprid. The highest level of imidacloprid found in these wells was 3.9 ppb. These wells, however, are not representative of wells used to supply ground water for drinking water. The wells were screened at extremely shallow depths (screens beginning only 4 to 10 feet from surface) due to the fact that the depth to ground water averaged about five feet. It was concluded by the researchers (EFED makes no comment on this at this time without further investigation ourselves) that these wells are "no more representative of what would likely occur in drinking water supplies than pesticide concentrations in samples taken from a weir draining an agricultural field are representative of what would occur in a community water supply drawing from a river or reservoir downstream."

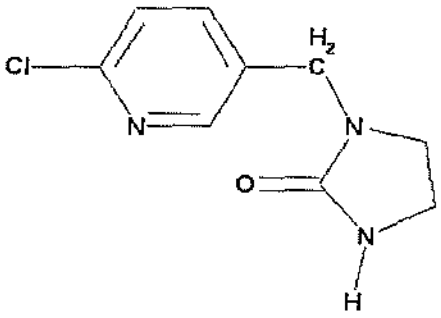
In a small turf plot surface water monitoring study by the registrant, the plot received from 1.7 to 3.5 in. water per hour for two hours. Up to 20% of the applied imidacloprid was found in runoff water 24 hours after application.

Appendix B. Structures of Imidacloprid and Selected Degradates



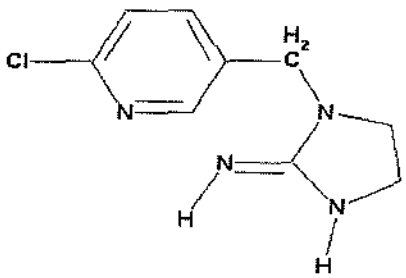
Imidacloprid (parent)
NTN 33893
IUPAC Name: (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine
CAS Name: (2E)-1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine
CAS No.: 138261-41-3

Formula: $C_9H_{10}ClN_5O_2$
MW: 255.7 g/mol
SMILES:
c1nc(Cl)ccc1CN2C(=NN(=O)=O)NCC2

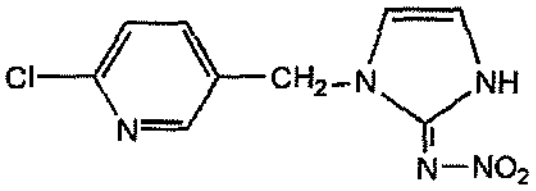


Imidacloprid Urea, I. 2-Ketone.
DIJ 9817; M12 (EU)
Name: 2-Imidazolidinone,1-[(6-chloro-3-pyridinyl)methyl]-
CAS No: 120868-66-8

Formula: C9H10ClN3O



Imidacloprid Guanidine; Desnitro Imidacloprid
NTN 33823 (Guanidine ; NTN 38014; WAK 4140; WLF 230; BEG 5322; Imidacloprid M09 (EU)
IUPAC Name: 1-[(6-Chloro-3-pyridyl)methyl]imidazolidin-2-imine
Other Name: 1-(6-chloro-3-pyridylmethyl)imidazolidin-2-ylideneamine



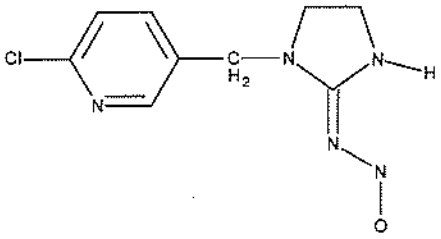
Imidacloprid olefin
NTN 35884; GAJ 2269; Imidacloprid M06 (EU)
Name: 1H-Imidazol-2-amine,1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-
CAS no.: 115086-54-9

Formula: $C_9H_8ClN_5O_2$

CAS no.: 115970-17-7

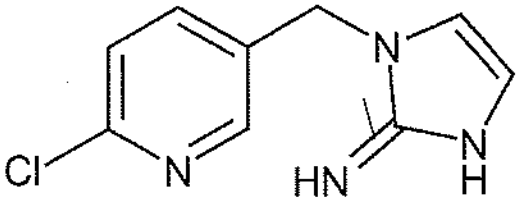
Formula: $C_9H_{11}ClN_4$
MW: 210.66 g/mol
SMILES: [H]/N=C/1\NCCN1Cc2ccc(nc2)Cl

May be present as free base (pictured) or associated with an acid such as HBr or H_2SO_4



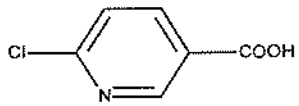
Imidacloprid nitrosimine
NAK3839
Name: N-[(E)-[1-[(6-chloro-3-pyridyl)methyl]imidazolidin-2-ylidene]amino]hydroxylamine

Formula: $C_9H_{10}ClN_5O$



Imidacloprid desnitro olefin
ANC 2126; Imidacloprid M23 (EU)
Name: 1-(6-chloro-3-pyridylmethyl)-4-imidazolin-2-ylidenediamine

Formula: $C_9H_9ClN_4$



6-Chloronicotonic acid
BNF 5518A
IUPAC: 6-Chloronicotinic acid
CAS No.: 5326-23-8

Formula: $C_6H_4ClNO_2$
MW: 157.56 g/mol
SMILES: O=C(O)c(ccc(n1)Cl)c1

Appendix C. Aquatic Exposure Modeling Inputs and Results

To estimate the amount of exposure to imidacloprid and, in some cases, imidacloprid total residues over time all of the available monitoring data were referred to, but the 2010 soil pore water monitoring results were most heavily relied upon. These data have limitations, for example, the enzyme linked immunosorbent assay (ELISA) analytical method is not entirely specific for imidacloprid (but the most cross-reactivity of the assay is expected to be associated with imidacloprid degradation products in the estuaries, which are also of some interest with regard to aquatic exposure[28].) In one report, the researchers provide evidence that analysis of the initial soil core samples taken within a few days after treatment might be overestimated imidacloprid residues due to matrix interference in the assay (Grue, 2012). Nonetheless, because of the potentially rapid motion and uneven distribution of imidacloprid residues over time, and because numerous environmental fate studies indicate there may be an increased association of imidacloprid residues with soil organic carbon or certain minerals with significant absorption / cation-exchange capacity, it is expected that the longest and most consistent residence time of imidacloprid residues should be in the soil-pore water.

In this study sediment cores were taken to a depth of 10 cm (with some additional cores taken to a depth of 25 cm to confirm whether most of the imidacloprid residues resided in the top 10 cm of sediment (which they seemed to do so since the concentrations in the 25 cm cores were much lower than in the corresponding 10 cm cores; the complete 25-cm data are not yet available, however). Initial sampling was done immediately the applications of imidacloprid at the lowest of the low tides of the day. The depth of standing water, if any, at the time of initial application and sampling was not specified, however. For the purposes of modeling expected concentrations at specific depths of incoming tidal water the measured concentrations in soil pore water (90% upper bound confidence limit of the mean) over time were used as the basis for estimating the mass of imidacloprid available for partitioning into the standing tidal waters.

For the purposes of modeling expected concentrations at specific depths of incoming tidal water the measured concentrations in soil pore water (90% upper bound confidence limit of the mean) over time were used as the basis for estimating the mass of imidacloprid available for partitioning into the standing tidal waters.

"From a theoretical perspective, the application of 2 lbs a.i. per acre to a given area will result in a total deposition of 0.224 g a.i. per m2 within the treatment area. At this deposition rate, depth of sediment cored, specific gravity, and the percent moisture of samples collected in this study, we would anticipate a theoretical maximum whole dry sediment measure of 1,556 ppb. Conversely, under the presumption that 100% of the IMI is solubilized in the water fraction, pore water measures should not exceed 5,013 ppb. For the 0.5 lb a.i./ac application, these values would be one quarter of those calculated for the 2 lb application: 389 ppb and 1,253 ppb, respectively. See Appendix C for calculation of theoretical values." (page 7 of 2010 sediment report.)

[28] For the three metabolites examined, Imidacloprid Olefin, DesNitro Imidacloprid, and Imidacloprid Urea the cross-reactivities were 32, 60 and 34%, respectively.

Imidacloprid Monitoring Data Summary and Use in Oyster Bed Exposure Estimation

The following non-guideline studies were received from the registrant (only the study by Felsot and Ruppert (2002) has been published):

"Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".
[This is a preliminary report on the results of the 2011 residue and effects monitoring; a full citation was not available and the data provides were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency. This report is expected to provide further information on the concentrations of imidacloprid in the water column, pore-water, and in sediments arising from applications to oyster beds. The report is also slated to provide further validation of the precision and accuracy of an ELISA analytical technique compared to the standard HPLC technique.]

Grue, Christian E.; J. Martin Grassley, John A. Frew, and A. Troiano. 2012. Use of an Enzyme--linked Immunosorbent Assay (ELISA) to Quantify Imidacloprid in Sediment Pore Water Following Application of Imidacloprid in Willapa Bay, Washington – Matrix Effects and Cross--reactivity. University of Washington unnumbered report.
[This report provided information on the sensitivity of the ELISA analytical method to imidacloprid metabolites which is used in this review to provide conservative estimates of chronic exposure to imidacloprid total residues based upon the ELISA 2010 monitoring results.]

Grue, C.E., J.M. Grassley, and J.A. Frew. 2011. Concentrations of imidacloprid in sediment pore water following application of imidacloprid in Willapa Bay, Washington - 2010. Report submitted to the Willapa Grays Harbor Oyster Growers Association. Washington Cooperative Fish and Wildlife Research Unit, University of Washington, Seattle, WA. 22 pp. (November 11, 2011).
[This report only contains results from monitoring with an ELISA method. The ELISA method, while unable to completely resolve the nature of the detected residues (because of cross-reactivity with imidacloprid degradates) has advantages for provide a conservative Tier 1 estimate of exposure from this use.]

Grue, Christian E. 2012. Use of an enzyme---linked immunosorbent assay (ELISA) to quantify imidacloprid in sediment pore water following application of imidacloprid in Willapa Bay, Washington – Matrix effects and cross---reactivity. University of Washington Seattle, WA Prepared for: Willapa Grays Harbor Oyster Growers Association (3/12/2012).

Felsot, A.S. and J.R. Ruppert. 2002. Imidacloprid residues in Willapa Bay (Washington State) water and sediment following application for control of burrowing shrimp. J Agric. Food Chem. 50:4417-4423.
[An earlier study with limited sampling of imidacloprid in standing water and sediment at 0-1, 14, and 28 days post-application to small plots. Also includes measurement of imidacloprid sorption coefficients directly in a Willapa Bay sediment sample mixed with sea water.]

[This is the published version of an earlier monitoring study.]

Moore, J. and D. Tufts. 2011. Willapa-Grays Harbor Oyster Growers Association 2011 annual report for burrowing shrimp control. Report submitted to the Washington State Dept. of Ecology (December 1, 2011).
[This report has apparently complete reports of the carbaryl residue monitoring done for the 2011 carbaryl applications, but only has "Preliminary Findings" regarding the 2011 imidacloprid Experimental Use Permit application in a section entitled "Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".]

Giddings, Jeffrey M.; Larry Turner, Jim Gagne, and Gary Dickson. 2011. Ecological Risk Assessment of Imidacloprid Applications to Control Burrowing Shrimp in Oyster Beds of Willapa Bay and Grays Harbor, WA. Compliance Services International (CSI) project 11706, Lakewood, WA; submitted to Washington State University under Subcontract no. 19303. (June 17, 2011 Draft report.)
[This report provides an overall summary of the available data for imidacloprid monitoring in the water above and near treated beds as well as in sediment pore water and will be cited in this review as appropriate.]

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Source Code for Program (KDCALC) Used to Estimate Partitioning of Imidacloprid into Standing Water of Incoming Tides

```
      PROGRAM KDCALC

C     THIS IS A PROGRAM TO CALCULATE THE PESTICIDE CONCENTRATION IN
C     WATER COLUMN AND THE PESTICIDE CONCENTRATION IN SEDIMENT BASED
C     ON THE ADSORPTION COEFFICIENT (Kd), THE DEPTH OF THE WATER AND
C     THE DEPTH OF SEDIMENT - CALCULATION IS BASED ON A 1.0 SQUARE
C     METER SURFACE AREA
C
      REAL APRATE,KD,DEPWAT,DEPSED,CONWAT,CONSED,MASWAT,MASSED,VOLWAT,
     2     VOLSED,PSTTOT,PSTSED,PSTWAT,BDSED,BDWAT,KDCHEK,TOTCHK
C
      INTEGER CODE
      CHARACTER*1 AGAIN
      CHARACTER*20 OUTFIL
C
C     DESCRIPTION OF VARIABLES
C
C     APRATE   APPLICATION RATE IN KG/HA
C     AREA     AREA OF THE SYSTEM = 1.0 SQUARE METERS
C     BDSED    BULK DENSITY OF THE SEDIMENT = 1,650 KG/M3
C     BDWAT    BULK DENSITY OF WATER = 1.0 KG/LITER
C     CONSED   INSTANTANEOUS CONCENTRATION IN THE SEDIMENT
C     CONWAT   INSTANTANEOUS CONCENTRATION IN THE WATER COLUMN
C     DEPSED   DEPTH OF THE SEDIMENT LAYER
```

```
C     DEPWAT   DEPTH OF THE WATER COLUMN
C     KD       SOIL ADSORPTION COEFFICIENT
C     MASSED   MASS OF SEDIMENT
C     MASWAT   MASS OF WATER
C     PSTTOT   TOTAL MASS OF PESTICIDE IN THE SYSTEM = APRATE * DECDRF
C     PSTSED   MASS OF PESTICIDE IN THE SEDIMENT
C     PSTWAT   MASS OF PESTICIDE IN THE WATER
C     DECDRF   DECIMAL FRACTION SPRAY DRIFT
C     PCTDRF   PERCENT SPRAY DRIFT
C     VOLSED   VOLUME OF SEDIMENT
C     VOLWAT   VOLUME OF WATER
C
      WRITE(*,5)
   5  FORMAT(////,3X,'                                KDCALC          ',/////
     2 3X,'           ENVIRONMENTAL FATE AND EFFECTS DIVISION         ',/
     3 3X,'                OFFICE OF PESTICIDE PROGRAMS               ',/
     4 3X,'            U.S. ENVIRONMENTAL PROTECTION AGENCY          ',//
     5 3X,'                          VERSION 1.0                      ',/
     6 3X,'                          OCT 1, 2002                       ')
C
      WRITE(*,10)
  10 FORMAT(//,3X,'THIS IS A PROGRAM TO CALCULATE THE PESTICIDE CONCENT
     2RATION',/
     3 3X,'IN THE WATER COLUMN AND IN THE SEDIMENT LAYER BASED ON THE',/
     4 3X,'AMOUNT APPLIED, THE ADSORPTION COEFFICIENT (Kd), THE DEPTH',/
     5 3X,'DEPTH OF THE WATER COLUMN AND THINKNESS OF THE SEDIMENT LAYER
     6',/
     7 3X,'CALCULATION IS BASED ON 1.0 SQUARE METER OF SURFACE AREA',///
     8 3X,'PLEASE ENTER A RUN NUMBER TO CONTINUE ---> ',$)
      READ(*,*) CODE
C
C  OPEN FILES FOR PROGRAM OUTPUT
C
      WRITE(*,11)
  11 FORMAT(///,3X,'PLEASE SELECT AN OUTPUT FILE NAME ---> ',$)
      READ(*,12) OUTFIL
  12 FORMAT(A20)
C
      OPEN(UNIT=6,FILE=OUTFIL,STATUS='UNKNOWN')
C
  99 WRITE(*,13)
  13 FORMAT(///,3X,'PLEASE ENTER THE PARTITION COEF (Kd) ---> ',$)
      READ(*,14) KD
  14 FORMAT(F8.0)
C
      AREA = 10000
C
      WRITE(*,15)
  15 FORMAT(///,3X,'PLEASE ENTER WATER COLUMN DEPTH (cm) ---> ',$)
      READ(*,16) DEPWAT
  16 FORMAT(F8.0)
C
C  CALCULATE THE VOLUME OF WATER IN LITERS
C
```

```
      VOLWAT = DEPWAT * AREA / 1000.0
C
      WRITE(*,17)
   17 FORMAT(///,3X,'PLEASE ENTER THICKNESS OF SEDIMENT (cm) ---> ',$)
      READ(*,18) DEPSED
   18 FORMAT(F8.0)
C
C  CALCULATE THE VOLUME OF SEDIMENT IN LITERS
C
      VOLSED = DEPSED * AREA / 1000.0
C
      WRITE(*,20)
   20 FORMAT(///,3X,'PLEASE ENTER APPLICATION RATE (IN KG/HA) ---> ',$)
C
      READ(*,21) APRATE
   21 FORMAT(F8.0)
C
      WRITE(*,22)
   22 FORMAT(///,3X,'PLEASE ENTER PERCENT SPRAY DRIFT ---> ',$)
      READ(*,23) PCTDRF
   23 FORMAT(F8.0)
C
      DECDRF = (PCTDRF/100.0)
C
C  CALCULATE THE MASS OF PESTICIDE ENTERING THE 1.0 SQUARE METER AREA
C  IN MILLIGRAMS (1 kg/ha = 100 mg/m2)
C
      PSTTOT = APRATE * DECDRF * 100.0
C
      BDSED = 1.65
      BDWAT = 1.00
C
      MASSED = BDSED * VOLSED
      MASWAT = BDWAT * VOLWAT
C
      PSTWAT = (PSTTOT * VOLWAT) / (MASSED * KD + VOLWAT)
C
      PSTSED = PSTTOT - PSTWAT
C
      CONWAT = PSTWAT / VOLWAT
      CONSED = PSTSED / MASSED
C
C  WRITE OUTPUT TO THE SCREEN AND TO THE OUTPUT FILE
C
       WRITE(*,50)CODE
       WRITE(6,50)CODE
   50 FORMAT(////,3X,'RUN No.',I4,'          * INPUT VALUES *        ',/
     2 3X,'-------------------------------------------------------',/
     3 3X,' RATE    SPRAY DRIFT  APPLIED   SOIL Kd   WATER   SEDIMENT',/
     4 3X,'(kg/ha)   (percent)   (mg/m2)   (l/kg)    (cm)      (cm)  ',/
     5 3X,'-------------------------------------------------------')
C
      WRITE(6,52)APRATE,PCTDRF,PSTTOT,KD,DEPWAT,DEPSED
      WRITE(*,52)APRATE,PCTDRF,PSTTOT,KD,DEPWAT,DEPSED
```

```
C
   52 FORMAT(3X,F6.2,3X,F7.1,5X,F8.2,4X,F6.1,3X,F7.1,3X,F6.1)
C
      WRITE(*,60)
      WRITE(6,60)
C
   60 FORMAT(////,3X,'MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT ',/
     2 3X,'-------------------------------------------------------------',/
     3 3X,'PEST-WAT  VOL-WAT  CONC-WAT   PEST-SED  MAS-SED  CONC-SED ',/
     4 3X,'  (mg)     (liter)   (mg/l)      (mg)      (kg)     (mg/kg)  ',/
     5 3X,'-------------------------------------------------------------')
C
      WRITE(6,62)PSTWAT,VOLWAT,CONWAT,PSTSED,MASSED,CONSED
      WRITE(*,62)PSTWAT,VOLWAT,CONWAT,PSTSED,MASSED,CONSED
C
   62 FORMAT(3X,F8.2,1X,F8.1,F10.3,2X,F9.3,1X,F8.3,2X,F8.3)
C
      KDCHEK = CONSED / CONWAT
      TOTCHK = PSTWAT + PSTSED
C
      WRITE(*,*)
      WRITE(*,65) KDCHEK
      WRITE(*,66) TOTCHK
C
   65 FORMAT('    CONSED / CONWAT = ',F8.2)
   66 FORMAT('    PSTWAT + PSTSED = ',F8.2)
C
      WRITE(*,70)
   70 FORMAT(/////,3X,'DO YOU WANT TO DO ANOTHER RUN (Y OR N) ---> ',$)
      READ(*,80) AGAIN
   80 FORMAT(A1)
C
      IF(AGAIN.EQ.'Y'.OR.AGAIN.EQ.'y')THEN
        WRITE(*,90)
   90   FORMAT(///3X,'PLEASE ENTER A NEW RUN NUMBER ---> ',$)
        READ(*,*) CODE
C
        APRATE = 0
        APRATE = 0
        AREA = 0
        BDSED = 0
        BDWAT = 0
        CONSED = 0
        CONWAT = 0
        DEPSED = 0
        DEPWAT = 0
        KD = 0
        MASSED = 0
        MASWAT = 0
        PSTTOT = 0
        PSTSED = 0
        PSTWAT = 0
        DECDRF = 0
        PCTDRF = 0
```

```
          VOLSED = 0
          VOLWAT = 0
C
          GOTO 99
C
        ENDIF
C
        STOP
        END
```

&&&&&&&&&&&&&&&&&&&&&

Sample Input Summary and Output Files for KDCALC Program

RUN No. 15 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (l/kg)	WATER (cm)	SEDIMENT (cm)
.48	100.0	47.72	1.0	3.0	3.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT (mg)	VOL-WAT (liter)	CONC-WAT (mg/l)	PEST-SED (mg)	MAS-SED (kg)	CONC-SED (mg/kg)
18.01	30.0	.600	29.712	49.500	.600

RUN No. 16 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (l/kg)	WATER (cm)	SEDIMENT (cm)
.06	100.0	6.44	1.0	3.0	3.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT (mg)	VOL-WAT (liter)	CONC-WAT (mg/l)	PEST-SED (mg)	MAS-SED (kg)	CONC-SED (mg/kg)
2.43	30.0	.081	4.010	49.500	.081

RUN No. 17 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (1/kg)	WATER (cm)	SEDIMENT (cm)
.02	100.0	2.13	1.0	3.0	10.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT	VOL-WAT	CONC-WAT	PEST-SED	MAS-SED	CONC-S

Appendix D. Ecological Toxicity Summary

Toxicity to Terrestrial Animals

Avian (Acute and Subacute Toxicity)

Table B-1. Avian Acute Oral Toxicity

Species	% a.i.	LD_{50} (mg/kg)	Toxicity Category	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	97.4	152.3	Moderately toxic	42055308/Toll /1990	Core
House Sparrow (*Passer domesticus*)	2.5G	41.0	Highly toxic	42055309/ Stafford/1990	Supplemental
Japanese Quail (*Coturnix japonica*)	95.3	31	Highly toxic	43310401 Grau/1988	Supplemental

Since the LD_{50} is 31 mg/kg, imidacloprid technical appears to be highly toxic to Japanese quail. A study on the granular product (2.5G) also suggests that exposure of the compound to small birds (house sparrow) can result in high toxicity (41 mg/kg).

Table B-2. Avian Subacute Dietary Toxicity

Species	% a.i.	5-day LC_{50} (ppm)	Toxicity Category	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	94.8	1,536	Slightly toxic	42055310/Toll/ 1990	Core
Mallard duck (*Anas platyrhynchos*)	94.8	> 4,797	Practically non-toxic	42055311/Toll /1990	Core

The LC_{50} values of 1,536 - 4,797 ppm suggest that imidacloprid is practically non-toxic to mallard ducks and slightly toxic to Bobwhite quail after dietary exposure.

Avian (Chronic Toxicity)

Table B-3. Avian Reproduction Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Toxicity Endpoints Affected	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	94.8	36/ >61	Egg shell thinning and decrease in adult weights	42055312/Toll /1991	Core

Mallard duck (*Anas platyrhynchos*)	94.8	125/ >125	Egg shell thinning and decrease in adult weights	42055313/Toll /1991	Supplemental
Mallard duck (*Anas platyrhynchos*)	94.8	47/61	Egg shell thinning	43466501	Supplemental

The chronic studies that were submitted show that imidacloprid exposure of 61 ppm to Bobwhite quail may result in egg shell thinning and decreased adult weight.

Mammals (Acute and Chronic Toxicity)

Table B-4 Mammalian Acute Toxicity

Species	% a.i.	LD50 (mg/kg)	Toxicity Category	MRID # Author/Year	Study Classification
Laboratory Rat (*Rattus norvegicus*)	2.5G	> 4,820	Practically non-toxic	42055324	Core
Laboratory Rat (*Rattus norvegicus*)	Tech	424	Moderately toxic	42055331	Core
Laboratory Rat (*Rattus norvegicus*)	97.6	LOAEL =151	-	41370301 43285801	Core
Laboratory mouse	10	1,838	Slightly toxic	42679601	Core

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, the intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects division (HED) substitute for wild mammal testing. Since imidacloprid is a neurotoxic chemical there is evidence of functional neurotoxicity in treated rats. A single oral dose caused a dose-related decrease in motor or locomotor activity with a LOAEL = 151 mg/kg. The LD50 = 424 mg/kg suggesting moderate toxicity.

Table B-5. Mammalian Reproductive Toxicity

Species	% a.i.	Toxicity Value NOAEL (mg/kg)	MRID #	Study Classification
Laboratory rat	tech	250 ppm	42256340	Core

The results of the mammalian reproduction studies suggest that imidacloprid may cause reproductive effects at an exposure level of 250 ppm and above.

Toxicity to Beneficial Insects

Table B-6. Nontarget Insect Studies

Species	% a.i.	Endpoint	Toxicity Category	MRID # Author/Year	Study Category
Honey bee (*Apis mellifera)*	99.8	LD_{50} (µg/bee) = 0.078 (contact)	Very highly toxic	42273003/Cole /1990	Core
Honey bee (*Apis mellifera)*	99.8	LD_{50} (µg/bee) = 0.0039 (oral)	Very highly toxic	42273003/Cole /1990	Core
Honey bee (*Apis mellifera)*	240 FS TEP 0.5 lb a.i./A	RT_{25} = 8hrs	N/A	42632901/ Hancock et al./1992	Core

Acute toxicity testing on honeybees suggest that imidacloprid is very highly toxic (0.0039 - 0.078 ug/bee) to non-target insects.

Toxicity to Freshwater Aquatic Organisms

Freshwater Fish (Acute)

Table B-7. Acute Toxicity for Freshwater Fish

Species	% a.i.	LC_{50} (ppm)	Toxicity Category	MRID # / Author/ Date	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	97.4	> 83	Practically non-toxic	42055315/ Bowman/1990	Core
Bluegill sunfish (*Lepomis macrochirus*)	97.4	> 105	Practically non-toxic	42055314/ Bowman/1990	Core

Acute toxicity testing on the preferred species, rainbow trout and bluegill sunfish, resulted in 96-hour LC_{50} values of 83 - 105 ppm. This suggest that imidacloprid is practically non-toxic to freshwater fishes on an acute basis.

Freshwater Fish (Chronic)

Table B-8. Freshwater Fish Chronic Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	95	1.2 / 2.5	Weight and length	42055320/ Bowman/1990	Supplemental

The results from a rainbow trout early life stage study suggest that imidacloprid exposure can result in growth effects (1.2 ppm) to freshwater fish.

Freshwater Invertebrates (Acute)

Table B-9. Freshwater Invertebrate Acute Toxicity

Species	% a.i.	48 Hour EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Daphnid (*Daphnia magna*)	95.4	85.2	Slight toxicity	42055317/ Young/1990	Core
Amphipod (*Hyalella azteca*)	tech	0.115	Very highly toxic	42256303/ England & Bucksath/1991	Core
Midge (*Chironomus tentans*)	tech.	0.069	Very highly toxic	42256304/ Gagliano/1991	Core
Midge (*Chironomus tentans*)	Desnitro (guanidine) degradate	--	--	43946602/ Bowers/1996	*In Review*
Amphipod (*Hyalella azteca*)	Desnitro (guanidine) degradate	--	--	43946601/ Roney and Bowers/1996	*In Review*
Midge (*Chironomus tentans*)	6-chloronicotinic acid degradate	--	--	44558901/ Bowers and Lam/1998	*In Review*
Midge (*Chironomus tentans*)	Urea degradate	--	--	43946604/ Dobbs and Frank/1996	*In Review*
Amphipod (*Hyalella azteca*)	Urea degradate	--	--	43946603/ Dobbs and Frank/ 1996	*In Review*

Imidacloprid is categorized as very highly toxic (0.069 - 0.115 ppm) to freshwater invertebrates on an acute basis.

Table B-10. Freshwater Invertebrate Chronic Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Daphnid (*Daphnia magna*)	95.9	1.8 / 3.6	Growth and movement	42055321/ Young/1990	Supplemental

Imidacloprid exposure to freshwater invertebrates can potentially result in growth effects at 3.6 ppm.

Toxicity to Estuarine and Marine Organisms

Estuarine and Marine Fish (Acute)

Table B-11. Estuarine/Marine Acute Toxicity

Species	% a.i.	96-hour LC50 (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Sheepshead Minnow (*Cyprinodon variegatus*)	92.2	163	Practically non-toxic	42055318/ Ward/1990	Core

Imidacloprid exposure to estuarine/marine fish is expected to be practically non-toxic on an acute basis (135 ppm).

Estuarine and Marine Fish (Chronic)

No estuarine/marine chronic studies have been submitted at this time.

Estuarine and Marine Invertebrates (Acute)

Table B-12. Estuarine/Marine Invertebrate Acute Toxicity

Species	% a.i.	48 Hour EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Mysid Shrimp (*Mysidopsis bahia*)	96.2	0.037	Very highly toxic	42055319/ Ward/1990	Core
Eastern Oyster (*Crassostrea virginica*)	95.8	> 145	practically non-toxic	42256305/ Wheat/1991	Supplemental

Imidacloprid is very highly toxic to estuarine/marine invertebrates (mysid shrimp) on an acute basis (0.037 ppm). However, it appears that bivalves may be more tolerant and may avoid acute exposure (> 145 ppm).

Estuarine and Marine Invertebrates (Chronic)

Table B-13. Estuarine/Marine Invertebrate Life-Cycle Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Mysid Shrimp (*Mysidopsis bahia*)	96.2	>0.0006 / 0.0013	Growth and Survival	42055322/ Ward/1990	Core

The results of this study suggest that chronic exposure of imidacloprid to estuarine/marine invertebrates can result in growth and survival effects (0.0013 ppm).

Aquatic Plants

Table B-14. Aquatic Plants

Species	% a.i.	EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Green Algae *Scenedesmus subspicatus*	92.8	> 10	N/A	42256374/ Heimbach/1989	Supplemental
Duckweed *Lemna gibba*	98.8	--	--	48648601/ Banman et al./ 2011	*In review*

EFED requires Tier I aquatic growth studies on 5 aquatic plants, including 1 vascular and 4 non-vascular taxa.

Terrestrial Plants

Table B-15. Terrestrial Plants

Study type	Formulation	EC_{25} (lb/A)	MRID #/ Author/Date	Study Classification
Vegetative Vigor	SC 240D G	--	48648602/Bach/ 2011	*In review*
Seedling Emergence	SC 240D G	--	48648603/Bach/ 2011	*In review*

EFED requires Tier I vegetative vigor and seedling emergence studies on 10 terrestrial plant species, including 4 monocot and 6 dicot species.

Appendix E. List of imidacloprid studies used in the risk assessment that were submitted to the European Food Safety Authority but not to the Agency.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid SL 200 on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer CropScience AG, unpublished report No.: DOM 21064, November 14, 2001, WAT2003-660.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid (tech.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: DOM 21035; Date: 2001-10-04, WAT2003-648.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid-desnitro on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer CropScience AG, unpublished report No.: DOM 21039, Date: 2001-10-26 WAT2003-649.

Dorgerloh, M. and Sommer, H. 2002. Acute toxicity of imidacloprid-nitroso to Larvae of *Chironomus riparius*. Bayer CropScience AG, unpublished report no.: DOM 22032, April 18, 2002, WAT2003-654.

Dorgerloh, M. and Sommer, H. 2002. Acute toxicity of imidacloprid-5-hydroxy to Larvae of *Chironomus riparius*; Bayer CropScience AG, unpublished report no.: DOM 22033, April 18, 2002 WAT2003-655.

Grau, R. 1996. NTN 33893 techn.: 5-Day Dietary LC_{50} to Japanese quail. Bayer CropScience AG, unpublished report No. GMU/VW-177. Date: 1996-03-14. Amended: 2002-01-28, AVS 98-00136.

Hendel, B. 2001. Influence of NTN 33893-AMCP on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 49; Date: 2001-5-10, WAT2003-651.

Hendel, B. 2001. Influence of NTN 33893-urea on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 48; Date: 2001-06-08, WAT2003-652.

Hendel, B. 2001. Influence of imidacloprid (tech.) of *Gammarus pulex* in a water-sediment system. Bayer CropScience AG, unpublished report No.: HDB/SP 01-00, April 5, 2001, PFL2003-191.

Hendel, B. and Sommer, H. 2001. Influence of Imidacloprid-desnitro-olefine on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 51; Date: 2001-11-26; WAT2003-650.

NEW APPLICATIONS

DATE: 2/10/2012

FILE NUMBER: 88867-R

FEP (OPPIN ENTRY) LV FEB 13 2012
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ **ASSIGN TO PM** / **(NO DATA)**

____ **JACKET TO SHELF (DATA)**

To the Document Center (ITRMD)

*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section:	**PM -5**		
Insecticide Branch:	**PM -10**	**PM-13**	
Herbicide Branch:	**PM-23**	**PM-25**	
Fungicide Branch:	**PM-20**	**PM-21**	**PM-22**
Insect/Rodent Branch:	**PM-1**	**PM-7**	

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team

Steve Schaible
(Team Member Signature)

2/27/12
(Date)

21-Day Screen Completed by Contractor

21-Day Expires on 3-2-12

Jacket # 88867-R
MRID# 487419

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN JETHABLE

5

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 2-10-12 3/23/09

Experts In-Processing Signature: B. C3 Date 2-17-12 Fee Paid: Yes __

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 88867-R	EPA Receipt Date: 2-10-12

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) [Pre-harvest - 920]	yes: X	no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes:	no:			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes: X	no:			
	b) Cite-All (Fee category experts use)	yes:	no:			
	c) Applicant owns all data (Fee category experts use)	yes:	no:			
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

The application package was missing confidential statement of Formula initially. Registrant was contacted on 02/17/2012 (the day jacket was received to us). Registrant sent the missing CSF on 02/22/2012. After reviewing it was found that CSF had previously registered product name and EPA Reg #. Registrant was contacted and corrections were received on 02/23/2012. Also, FES had previously registered product name and Reg #. Corrections made on 02/23/12.

Inerts approved for food use under 40 CFR 180.920, pre-harvest application to growing crops.

Regarding the studies, initially study #02 had 2 pgs illegible. Registrant sent the corrections on 02/23/12. (Details in the email attached)

PRN - 11-3 review - Passed

Jacket - passed

S.S/02-24-12

MRID - 487419

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

RE: Submission in support of products , "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Amanda Bragg to: Srijana Shrestha 02/23/2012 01:59 PM

4 attachments


EPA Form 8750-4 Protector 2F (2).jpg


EPA Form 8750-4 Protector 2F.jpg


EPA Form 8750-27 Protector 0.5G.jpg


EPA Form 8750-27 Protector 2F.jpg

Srijana,

I hope this is the last of the changes.

Thanks,

Amanda

-----Original Message-----
From: Srijana Shrestha [mailto:Shrestha.Srijana@epamail.epa.gov]
Sent: Wednesday, February 22, 2012 1:50 PM
To: Amanda Bragg; aschreib@centurytel.net
Cc: Sree Nair
Subject: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Dear Ms. Bragg:

The second attachment still has the me too (previously registered product) as product name. Please edit it with correct product name.
Also, regarding studies associated with this submission, Study(02) titled, "IR-4 Minor Use Submission in Support of Tolerances for Imidacloprid In or On Fish and Shell fish" has pgs 60 and 61 illegible.
Please send revised legible pages or mark "BEST AVAILABLE COPY" if that is the case.

As I mentioned in our ph conversation, due to the time line we have, I will have to pass all the materials to the appropriate EPA Risk Manager on the 15th day i.e. 02/25/12 noon (Saturday). I will be out of office on 02/24/12 so, please send the corrections by 02/23/12 noon.

Please direct all future contacts and correspondence after 02/25/12 to EPA Risk Manager. Feel free to call me back at 703-305-6471, if you have any questions.

Thanking you,
Srijana Shrestha
Macfadden, EPA Contractor
2777 S. Crystal Drive, S 4910 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060

From: "Amanda Bragg" <abragg@centurytel.net>
To: Srijana Shrestha/DC/USEPA/US@EPA
Date: 02/22/2012 04:02 PM
Subject: FW: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Srijana,

Attached are the requested documents with the changes we discussed. Please let me know if any of them are still illegible or if we need to make any more changes.

Thank you,

Amanda Bragg
Assistant Administrator
Ag Development Group
Ph: 509-266-4348
Fax: 509-266-4317

From: Amanda Bragg [mailto:abragg@centurytel.net]
Sent: Wednesday, February 22, 2012 8:48 AM
To: 'Shrestha.Srijana@epamail.epa.gov'
Subject: FW: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Srijana,

Attached please find the Confidential Statements of Formula for both submissions.

Thank you,

Amanda Bragg
Assistant Administrator
Ag Development Group
Ph: 509-266-4348
Fax: 509-266-4317

From: Alan Schreiber [mailto:aschreib.as@gmail.com]
Sent: Tuesday, February 21, 2012 6:26 PM
To: Amanda Bragg
Subject: Fwd: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

---------- Forwarded message ----------
From: "Srijana Shrestha" <Shrestha.Srijana@epamail.epa.gov>
Date: Feb 17, 2012 10:32 AM
Subject: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

To: <aschreib@centurytel.net>
Cc: "Sree Nair" <Nair.Sree@epamail.epa.gov>

Dear Mr. Schreiber:

This is regarding your submission in support of products, "Protector 2F" (EPA Reg # 888867-E) and "Protector 0.5G (EPA Reg# 88867-R). We have found following issue with your submission:

"Confidential Statement of Formula (EPA Form 8570-4)" is missing in both submissions.

Please send the missing form by email. Feel free to call me back at 703-305-6471, if you have any questions. I will be happy to assist you in anyway.

Thanking you,
Srijana Shrestha
Macfadden, EPA Contractor
2777 S. Crystal Drive, S 4910 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060(See attached file: EPA Form 8750-4 Protector 0.5G.jpg) (See attached file: EPA Form 8750-4 Protector 2F (2).jpg)(See attached file: EPA Form 8750-4 Protector 2F.jpg)

Script for Rejection Phone calls

Contact Name: Alan Schreiber / Amanda Bragg
Phone #: 509-266-4348
Email: aschreib@centurytel.net

passed

First Call/Initials:	**Second Call/Initials:**	
Date: 02-17-2012	**Date:** 02-22-2012	02-23-2012
Time: 9:14 am	**Time:** 10:45am	1:45pm

This is Srijana Shrestha **, EPA contractor.**

I'm calling regarding your submission in support of the product Protector 2F (EPA Reg # 88867-E) and Protector 0.5G (EPA Reg # 88867-R)

We have found the following deficiencies regarding:
PR Notice 2011-3: (Yes) or No
Volume/Study Title:
Study (2) for MRID-487419 and 2 pgs. illegible

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: (Yes) or No
missing CSF, errors in CSF and AFES (details in Pg. 3 and email)

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: Srijana Shrestha.

Second Call/Email:
If we do not receive the corrections by 02/24/12**, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 16, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-461090
EPA File Symbol or Registration Number: 88867-R
Product Name: PROTECTOR 0.5G
EPA Receipt Date: 10-Feb-2012
EPA Company Number: 88867
Company Name: WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

ALAN SCHREIBER
WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION
P.O. BOX 3
OCEAN PARK, WA 98640

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R170.0
NEW USE;EACH ADDITIONAL NEW FOOD USE;NO FEE: LINKED TO A PRIA APPLICATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{911544"~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☑ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 5

Receipt No. S- 911544

EPA File Symbol/Reg. No. 88867-R

Pin-Punch Date: 2/10/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R170.1

Granted: R170.1

Amount Due: $ 0 124

Inerts approved. S.S/ 02-24-12

Parent/Child Decisions:

88867-E 591154S

☒ Inert Cleared for Intended Use ☒ Uncleared Inert in Product

Reviewer: [signature] Date: 2/15/12

Remarks:

NO CSF INCLUDED

Confidential Statement of Formula may be entitled to confidential treatment